

# Cancer Association of South Africa (CANSA)



## Fact Sheet on Cancer of the Gums

### Introduction

The gums (or gingiva, singular and plural) are part of the soft tissue lining of the mouth. The gums surround the teeth and provide a seal around them.

[Picture Credit: Gums]

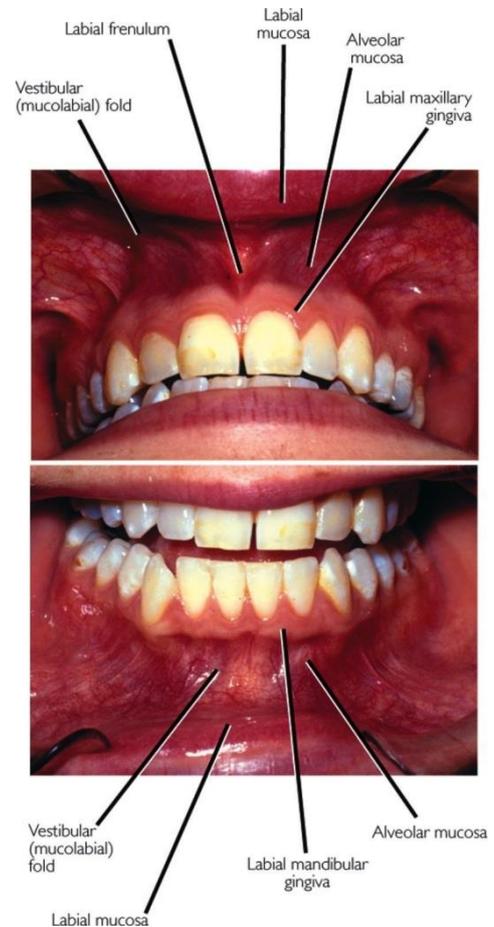
Compared with the soft tissue linings of the lips and cheeks, most of the gingivae are tightly bound to the underlying bone which helps resist the friction of food passing over them. Thus when healthy, it presents an effective barrier to the barrage of periodontal insults to deeper tissue. Healthy gums are usually coral pink, but may contain melanin pigmentation (Wikipedia).

The gums (gingiva) comprises connective tissue that consists of two layers. The outermost gingival layer is a continuation of the mucous membranes of the oral cavity. The layer beneath that is composed of fibrous tissue. The gingiva fills the spaces between the teeth and also surrounds the roots of every tooth. The gingiva is attached to the cementum layer of the root as well as to the jaw bone (Prenhall).

### Cancer of the Gums

Gum cancer is a type of malignancy that occurs when there is an uncontrolled growth of cancer cells in the gums. Gum cancer is a type of oral cancer and a relatively rare form of cancer in general.

Gum cancer is most treatable and curable if caught in the earliest stage of the disease. Gum cancer grows relatively slowly, but untreated and/or advanced gum cancer can spread into the deeper tissues of the mouth and neck. In advanced stages, gum cancer can spread through the lymph nodes and blood to other parts of the body where the cancer cells can form another cancerous tumour. This is called metastasis. Gum cancer and other forms of oral cancer have a high risk of recurring after treatment (Right Diagnosis).



## Incidence of Gum Cancer in South Africa

According to the National Cancer Registry (2012) the following number of Cancer of the Gums cases was histologically diagnosed in South Africa during 2012:

Group - Males 2012	Actual No of Cases	Estimated Lifetime Risk	Percentage of All Cancers
All males	28	1:4 753	0,08%
Asian males	0	-	-
Black males	14	1:7 430	0,12%
Coloured males	6	1:1 192	0,14%
White males	8	1:4 444	0,04%

Group - Females 2012	Actual No of Cases	Estimated Lifetime Risk	Percentage of All Cancers
All females	21	1:7 709	0,06%
Asian females	1	1:2 914	0,10%
Black females	8	1:14 183	0,05%
Coloured females	4	1:4 468	0,15%
White females	7	1:4 241	0,05%

The frequency of histologically diagnosed cases of Cancer of the Gums in South Africa for 2012 was as follows (National Cancer Registry, 2012):

Group - Males 2012	0 – 19 Years	20 – 29 Years	30 – 39 Years	40 – 49 Years	50 – 59 Years	60 – 69 Years	70 – 79 Years	80+ Years
All males	0	0	0	4	6	8	7	3
Asian males	0	0	0	0	0	0	0	0
Black males	0	0	0	4	2	5	2	1
Coloured males	0	0	0	0	2	2	2	0
White males	0	0	0	0	2	1	3	2

Group - Females 2012	0 – 19 Years	20 – 29 Years	30 – 39 Years	40 – 49 Years	50 – 59 Years	60 – 69 Years	70 – 79 Years	80+ Years
All females	0	0	1	1	5	7	6	1
Asian females	0	0	0	0	0	0	1	0
Black females	0	0	0	0	3	1	3	1
Coloured females	0	0	1	1	1	1	0	0
White females	0	0	0	0	1	4	1	0

N.B. In the event that the totals in any of the above tables do not tally, this may be the result of uncertainties as to the age, race or sex of the individual. The totals for 'all males' and 'all females', however, always reflect the correct totals.

## Causes and Risk Factors for Gum Cancer

Men get gum cancer more often than women and people over the age of 40 are affected more often than younger people. However, more recently, gum cancer is occurring in greater numbers in younger people.

The possibility of getting gum cancer is increased dramatically in those who smoke, those who chew tobacco and those who don't take care of their oral health with regular brushing, flossing and dental checkups.

People at risk for developing gum cancer include:

- smokers (cigarettes, cigars and pipes)
- using smokeless tobacco (chewing tobacco, snus)

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- people who drink alcohol excessively
  - being infected with the human papillomavirus (HPV)
  - a diet that is low in fruits and vegetables
- (E-How; Right Diagnosis; MedicineNet.Com).

### Signs and Symptoms of Gum Cancer

Regular medical or dental check-ups can detect the early stages of oral cancer or conditions that may lead to oral cancer.

Common symptoms of oral cancer include:

- patches inside the mouth or on the lips that are white, a mixture of red and white, or red
  - white patches (leukoplakia) are the most common - white patches sometimes become malignant

[Picture Credit: Leukoplakia]



- mixed red and white patches (erythroleukoplakia) are more likely than white patches to become malignant
- red patches (erythroplakia) are brightly coloured, smooth areas that often become malignant

[Picture Credit: Erythroplakia]

- a sore on the lip or in the mouth that won't heal
- bleeding in the mouth
- loose teeth
- difficulty or pain when swallowing
- difficulty wearing dentures
- a lump in the neck
- earache



Anyone with these symptoms should see a doctor or dentist so that any problem can be diagnosed and treated as early as possible. Most often, these symptoms do not mean cancer. An infection or another problem can cause the same symptoms.

### Diagnosis of Gum Cancer

If the doctor suspects a patient may have oral cancer, one or more of the following tests may be used to find out if he/she has cancer and whether it has spread:

**Biopsy** - if any abnormalities are discovered during the exam, a small tissue sample, or biopsy, usually is taken. This biopsy is important, as it is the only sure way to know if the abnormal area is cancer.

A biopsy may be obtained by:

- Brush biopsy or exfoliative cytology - this relatively new type of biopsy is painless and does not require anesthetic. The dentist or doctor rotates a small stiff-bristled brush on the area, causing abrasion or pinpoint bleeding. Cells from the area are collected and examined under a microscope by a pathologist. If results are inconclusive or show cancer, an incisional biopsy will be completed.
- Incisional biopsy - this is the traditional, most frequently used type of biopsy. The doctor or dentist surgically removes part or all of the tissue where cancer is suspected. Usually, this procedure is completed in the doctor's office or clinic under local anesthesia. But if the tumour is inside the throat, the biopsy may be done in an operating room under general anesthesia.
- Fine-needle-aspiration biopsy (FNA) - this type of biopsy often is used if a patient has a lump in the neck that can be felt. In this procedure, a thin needle is inserted into the area. Then cells are withdrawn and examined under a microscope.

Mucosal staining - a blue dye called toluidine blue O is applied to the area where cancer is suspected. If any blue areas remain after rinsing, they probably will be investigated with a biopsy.

Chemiluminescent light (the emission of light or luminescence as the result of a chemical reaction) - after having rinsed the mouth with a mild acid solution, the mouth is examined with a special light. Healthy cells do not reflect the light, whereas cancerous cells will reflect the light.

[Picture Credit: Chemiluminescence]



Imaging tests, which may include:

- Computed axial tomography (CAT) scans
- Positron emission tomography (PET) scans
- Magnetic resonance imaging (MRI) scans
- Chest and dental X-rays
- Barium swallow - also called an upper GI (gastrointestinal) series, this set of X-rays of the esophagus and stomach may be used to look for other cancers and determine how well the patient swallows
- Endoscopy

(MD Anderson Cancer Center).

### Staging of Gum Cancer

TNM stands for Tumour, Node and Metastasis. The system describes:

- The size of a primary tumour (**T**)
- Whether the cancer has spread to the lymph nodes (**N**)
- Whether the cancer has spread to a different part of the body (**M**)

### T stages

There are 4 main T stages of mouth and oropharyngeal cancer

**T1** means the tumour is contained within the tissue of the mouth or oropharynx and is no larger than 2cm

**T2** means the tumour is larger than 2cm, but smaller than 4cm

**T3** means the tumour is bigger than 4cm

- T4a** means the tumour has grown further than the mouth or oropharynx and into nearby body tissues such as bone, tongue, the air cavities of the face (sinuses) or the skin
- T4b** means the tumour has spread into nearby areas such as the space around and behind the jaws, the back of the upper jaw where the large jaw muscles attach, the base of the skull, or the area of the neck that surrounds the main arteries (carotid arteries)

### ***N stages***

There are 4 main lymph node stages in cancer of the mouth and oropharynx. One of these, stage N2, is broken down into 3 sub stages. The important points here are whether there is cancer in the lymph nodes in the neck and if so, the size of the node and which side of the neck it is on.

- N0** no cancer cells in the lymph nodes
- N1** there are cancer cells in 1 lymph node on the same side of the neck as the cancer, but the node is less than 3cm across
- N2a** there is cancer in 1 lymph node on the same side of the neck, and the node is more than 3cm across but less than 6cm across
- N2b** there is cancer in more than 1 lymph node, but none of these nodes are more than 6cm across. All the affected nodes are on the same side of the neck as the cancer.
- N2c** there is cancer in nodes on the other side of the neck, or in nodes on both sides, but none of these nodes are more than 6cm across
- N3** at least 1 node containing cancer is more than 6cm across

### ***M stages***

There are two M stages for cancers of the mouth and oropharynx

- M0** there is no cancer spread to other parts of the body
- M1** the cancer has spread to other parts of the body, such as the lungs

Together, the T, N and M stages give a complete description of the stage of your cancer. For example, if you have a T2, N0, M0 cancer, you have a tumour larger than 2cm but not larger than 4cm. There are no cancer cells in the lymph nodes and there is no spread of your cancer to other parts of the body.

### ***Number Stages of gum cancer***

#### **Stage 0**

Cancer is '*in situ*', meaning it is isolated and has not traveled into a deeper layer of tissue or the lymph nodes, small almond-shape glands that help fight infection or trap tumor cells

#### **Stage I**

Tumor is 2 centimeters or smaller and the tumour has not spread to lymph nodes or other parts of the body

#### **Stage II**

Tumor is between 2 and 4 centimeters and the tumour has not spread to lymph nodes or other parts of the body

**Stage III:** Tumor is either:

Larger than 4 centimeters or any size and has traveled to one lymph node on the same side of the head or neck. The lymph node with cancer measures 3 centimeters or less. The tumour has not spread to other parts of the body

**Stage IV:** Tumor is any size and has invaded deeply into muscle or facial skin or the jaws and has spread to:

More than one lymph node on the same side of the head or neck as the main tumour

Lymph nodes on one or both sides of the neck

Any lymph node that measures more than 6 centimeters

**Recurrent:** The oral cancer has reappeared after it was treated and may reappear in the oral cavity or another part of the body

### **Grades of Gum Cancer**

The grade of a cancer indicates that the cells look like under a microscope. The cells are graded according to how normal or abnormal they appear.

There are 4 grades of oral and oropharyngeal cancer cells:

Grade 1 (low grade)

The cancer cells look very much like normal mouth or oropharyngeal cells

Grade 2 (intermediate grade)

The cancer cells look slightly different to normal mouth or oropharyngeal cells

Grade 3 (high grade)

The cancer cells look very abnormal and not much like normal mouth or oropharyngeal cells

Grade 4 (high grade)

The cancer cells look very different to normal mouth or oropharyngeal cells (Cancer Research UK; MD Anderson Cancer Center).

### **Treatment of Gum Cancer**

The type of treatment your doctor will recommend depends on the tumour site and how far the cancer has spread.

#### Stage 0 (carcinoma in situ)

Although cancer in this stage has not become invasive (started to grow into deeper layers of tissue), it can do so if not treated. The usual treatment is to remove the top layers of tissue along with a small margin of normal tissue. This is known as *surgical stripping* or *thin resection*. Close follow-up to see if any cancer has come back (recurrence) is important.

Carcinoma *in situ* that keeps coming back after resection may require radiation therapy. Nearly all patients at this stage survive a long time without the need for more intensive treatment. Patients should be warned that continuing to smoke increases the risk for recurrence of that a new cancer will develop.

### Stages I and II

Most patients with stage I or II oral cavity and oropharyngeal cancer can be successfully treated with either surgery or radiation therapy. Chemotherapy may be combined with radiation, especially to treat any cancer left after surgery. Both surgery and radiation work well in treating these cancers. The choice of treatment is influenced by the expected side effects, including how the treatment might affect the appearance and ability to speak and swallow.

Lower gums - cancer in the lower gums is usually treated with surgery, which may include removing part of the mandible (jaw bone). Radiation (often combined with chemotherapy) may be added if all of the cancer could not be removed. Radiation may be used as the main treatment, but it carries a risk of damage to the jaw bone. Surgery to remove the lymph nodes in the neck is often recommended.

Upper gums and hard palate - cancers in the upper gum or hard palate (the front of the roof of the mouth) are also usually managed with surgery. Radiation (often with chemotherapy) may be added as well if needed because some of the cancer was left behind. Lymph nodes in the neck may be removed.

### Stages III and IV

More advanced oral cavity and oropharyngeal cancers generally require a combination of either surgery and radiation, radiation and chemotherapy (or cetuximab - a type of immunotherapy), or a combination of all three. The effect of combining radiation with both chemotherapy and cetuximab is also being studied. The choice of treatment is influenced by where the cancer is, how much it has spread, the expected side effects, and the patient's current health status.

Stages III and IV include cancers that have spread to lymph nodes in the neck. When lymph node spread is known to have occurred (for example, based on a fine needle biopsy), a neck dissection (removal of the lymph nodes in the neck) needs to be done. But even when the neck lymph nodes aren't known to contain cancer, the tumours in this stage are large and advanced, and have a high risk of spreading to the lymph nodes. Because of this, neck dissection is often a part of treatment for stage III and IV cancers.

Radiation therapy often is required after surgery, particularly if the tumour has spread to the lymph nodes. Sometimes chemotherapy is given as well, especially if the cancer has worrisome features. The amount of tissue removed during surgery depends on the extent of cancer, whilst the method of reconstruction depends on the surgical defect created.

Primary tumours that are too large to be completely removed by surgery are often treated with radiation, either alone or with chemotherapy (or cetuximab). Some doctors give chemotherapy as the first treatment, followed by chemotherapy in combination with radiation (chemotherapy and radiation given together), although not all doctors agree with this approach. Sometimes, these treatments may shrink the tumour enough so that surgery can be done.

Cancers that have already spread to other parts of the body are usually treated with chemotherapy, cetuximab, or both. Other treatments such as radiation may also be used to help relieve symptoms from the cancer or to help prevent problems from occurring.

### Recurrent Oral Cavity or Oropharyngeal Cancer

When cancer come backs after treatment, it is called *recurrent cancer*. Recurrence can be local (in or near the same place it started), regional (in nearby lymph nodes), or distant (spread to bone or organs such as the lungs). Treatment options for recurrent cancers depend on the location and size of the cancer, what treatments have already been used and on the person's general health.

If the cancer comes back in the same area and radiation therapy was used as the first treatment, surgery is often the next treatment if possible. Usually, external beam radiation therapy cannot be repeated in the same site except in selected cases. However, brachytherapy can often be used to control the cancer if it has recurred in the place of origin. If surgery was used first, more surgery, radiation therapy, chemotherapy, cetuximab, or a combination of these may be considered.

If the cancer comes back in the lymph nodes in the neck, these are often removed with surgery. This may be followed by radiation.

If the cancer comes back in a distant area, chemotherapy (and/or cetuximab) is the preferred form of treatment. This may shrink or slow the growth of some cancers for a while and help relieve symptoms, but these cancers are very difficult to cure. If further treatment is recommended, it is important for the patient to speak to the doctor regarding the goal of treatment — whether it is to try to cure the cancer or to keep it under control for as long as possible or to relieve symptoms. This can help the patient to weigh up the pros and cons of each treatment. As these cancers are hard to treat, clinical trials of newer treatments may be a good option for some people.

(American Cancer Society; Oral Cancer Foundation).

Surgery - there are a number of different operations to remove cancer of the mouth or oropharynx. For some very early stage cancers you may be able to have laser surgery under local anaesthetic or general anaesthetic but this is not common. Laser surgery uses a very thin beam of light to cut away the cancer cells.

Most of the operations for mouth or oropharyngeal cancer are major surgery. One will usually have a general anaesthetic. So one will be asleep for the whole operation. The amount of tissue the surgeon takes away will depend on where the cancer is. For example, if a large part of the tongue is also involved one may need to have a lot of the tongue removed (a glossectomy).

Some of these operations cause changes to the way one looks, eat, speaks and cope with life. If one is having major head and neck surgery, one will need to talk over all the options in detail with the surgeon.

(Cancer Research UK).

### **About Clinical Trials**

Clinical trials are research studies that involve people. These studies test new ways to prevent, detect, diagnose, or treat diseases. People who take part in cancer clinical trials have an opportunity to contribute to scientists' knowledge about cancer and to help in the development of improved cancer treatments. They also receive state-of-the-art care from cancer experts.

### Types of Clinical Trials

Cancer clinical trials differ according to their primary purpose. They include the following types:

**Treatment** - these trials test the effectiveness of new treatments or new ways of using current treatments in people who have cancer. The treatments tested may include new drugs or new combinations of currently used drugs, new surgery or radiation therapy techniques, and vaccines or other treatments that stimulate a person's immune system to fight cancer. Combinations of different treatment types may also be tested in these trials.

**Prevention** - these trials test new interventions that may lower the risk of developing certain types of cancer. Most cancer prevention trials involve healthy people who have not had cancer; however, they often only include people who have a higher than average risk of developing a specific type of cancer. Some cancer prevention trials involve people who have had cancer in the past; these trials test interventions that may help prevent the return (recurrence) of the original cancer or reduce the chance of developing a new type of cancer

**Screening** - these trials test new ways of finding cancer early. When cancer is found early, it may be easier to treat and there may be a better chance of long-term survival. Cancer screening trials usually involve people who do not have any signs or symptoms of cancer. However, participation in these trials is often limited to people who have a higher than average risk of developing a certain type of cancer because they have a family history of that type of cancer or they have a history of exposure to cancer-causing substances (e.g., cigarette smoke).

**Diagnostic** - these trials study new tests or procedures that may help identify, or diagnose, cancer more accurately. Diagnostic trials usually involve people who have some signs or symptoms of cancer.

**Quality of life or supportive care** - these trials focus on the comfort and quality of life of cancer patients and cancer survivors. New ways to decrease the number or severity of side effects of cancer or its treatment are often studied in these trials. How a specific type of cancer or its treatment affects a person's everyday life may also be studied.

### Where Clinical Trials are Conducted

Cancer clinical trials take place in cities and towns in doctors' offices, cancer centres and other medical centres, community hospitals and clinics. A single trial may take place at one or two specialised medical centres only or at hundreds of offices, hospitals, and centres.

Each clinical trial is managed by a research team that can include doctors, nurses, research assistants, data analysts, and other specialists. The research team works closely with other health professionals, including other doctors and nurses, laboratory technicians, pharmacists, dieticians, and social workers, to provide medical and supportive care to people who take part in a clinical trial.

### Research Team

The research team closely monitors the health of people taking part in the clinical trial and gives them specific instructions when necessary. To ensure the reliability of the trial's results, it is important for the participants to follow the research team's instructions. The instructions may include keeping logs or answering questionnaires. The research team may

also seek to contact the participants regularly after the trial ends to get updates on their health.

### Clinical Trial Protocol

Every clinical trial has a protocol, or action plan, that describes what will be done in the trial, how the trial will be conducted, and why each part of the trial is necessary. The protocol also includes guidelines for who can and cannot participate in the trial. These guidelines, called eligibility criteria, describe the characteristics that all interested people must have before they can take part in the trial. Eligibility criteria can include age, sex, medical history, and current health status. Eligibility criteria for cancer treatment trials often include the type and stage of cancer, as well as the type(s) of cancer treatment already received.

Enrolling people who have similar characteristics helps ensure that the outcome of a trial is due to the intervention being tested and not to other factors. In this way, eligibility criteria help researchers obtain the most accurate and meaningful results possible.

### National and International Regulations

National and international regulations and policies have been developed to help ensure that research involving people is conducted according to strict scientific and ethical principles. In these regulations and policies, people who participate in research are usually referred to as “human subjects.”

### Informed Consent

Informed consent is a process through which people learn the important facts about a clinical trial to help them decide whether or not to take part in it, and continue to learn new information about the trial that helps them decide whether or not to continue participating in it.

During the first part of the informed consent process, people are given detailed information about a trial, including information about the purpose of the trial, the tests and other procedures that will be required, and the possible benefits and harms of taking part in the trial. Besides talking with a doctor or nurse, potential trial participants are given a form, called an informed consent form, that provides information about the trial in writing. People who agree to take part in the trial are asked to sign the form. However, signing this form does not mean that a person must remain in the trial. Anyone can choose to leave a trial at any time—either before it starts or at any time during the trial or during the follow-up period. It is important for people who decide to leave a trial to get information from the research team about how to leave the trial safely.

The informed consent process continues throughout a trial. If new benefits, risks, or side effects are discovered during the course of a trial, the researchers must inform the participants so they can decide whether or not they want to continue to take part in the trial. In some cases, participants who want to continue to take part in a trial may be asked to sign a new informed consent form.

New interventions are often studied in a stepwise fashion, with each step representing a different “phase” in the clinical research process. The following phases are used for cancer treatment trials:

### Phases of a Clinical Trial

Phase 0. These trials represent the earliest step in testing new treatments in humans. In a phase 0 trial, a very small dose of a chemical or biologic agent is given to a small number of people (approximately 10-15) to gather preliminary information about how the agent is processed by the body (pharmacokinetics) and how the agent affects the body (pharmacodynamics). Because the agents are given in such small amounts, no information is obtained about their safety or effectiveness in treating cancer. Phase 0 trials are also called micro-dosing studies, exploratory Investigational New Drug (IND) trials, or early phase I trials. The people who take part in these trials usually have advanced disease, and no known, effective treatment options are available to them.

Phase I (also called phase 1). These trials are conducted mainly to evaluate the safety of chemical or biologic agents or other types of interventions (e.g., a new radiation therapy technique). They help determine the maximum dose that can be given safely (also known as the maximum tolerated dose) and whether an intervention causes harmful side effects. Phase I trials enrol small numbers of people (20 or more) who have advanced cancer that cannot be treated effectively with standard (usual) treatments or for which no standard treatment exists. Although evaluating the effectiveness of interventions is not a primary goal of these trials, doctors do look for evidence that the interventions might be useful as treatments.

Phase II (also called phase 2). These trials test the effectiveness of interventions in people who have a specific type of cancer or related cancers. They also continue to look at the safety of interventions. Phase II trials usually enrol fewer than 100 people but may include as many as 300. The people who participate in phase II trials may or may not have been treated previously with standard therapy for their type of cancer. If a person has been treated previously, their eligibility to participate in a specific trial may depend on the type and amount of prior treatment they received. Although phase II trials can give some indication of whether or not an intervention works, they are almost never designed to show whether an intervention is better than standard therapy.

Phase III (also called phase 3). These trials compare the effectiveness of a new intervention, or new use of an existing intervention, with the current standard of care (usual treatment) for a particular type of cancer. Phase III trials also examine how the side effects of the new intervention compare with those of the usual treatment. If the new intervention is more effective than the usual treatment and/or is easier to tolerate, it may become the new standard of care.

Phase III trials usually involve large groups of people (100 to several thousand), who are randomly assigned to one of two treatment groups, or "trial arms": (1) a control group, in which everyone in the group receives usual treatment for their type of cancer, or (2) an investigational or experimental group, in which everyone in the group receives the new intervention or new use of an existing intervention. The trial participants are assigned to their individual groups by random assignment, or randomisation. Randomisation helps ensure that the groups have similar characteristics. This balance is necessary so the researchers can have confidence that any differences they observe in how the two groups respond to the treatments they receive are due to the treatments and not to other differences between the groups.

Randomisation is usually done by a computer program to ensure that human choices do not influence the assignment to groups. The trial participants cannot request to be in a particular group, and the researchers cannot influence how people are assigned to the groups. Usually, neither the participants nor their doctors know what treatment the participants are receiving.

People who participate in phase III trials may or may not have been treated previously. If they have been treated previously, their eligibility to participate in a specific trial may depend on the type and the amount of prior treatment they received.

In most cases, an intervention will move into phase III testing only after it has shown promise in phase I and phase II trials.

Phase IV (also called phase 4). These trials further evaluate the effectiveness and long-term safety of drugs or other interventions. They usually take place after a drug or intervention has been approved by the medicine regulatory office for standard use. Several hundred to several thousand people may take part in a phase IV trial. These trials are also known as post-marketing surveillance trials. They are generally sponsored by drug companies.

Sometimes clinical trial phases may be combined (e.g., phase I/II or phase II/III trials) to minimize the risks to participants and/or to allow faster development of a new intervention.

Although treatment trials are always assigned a phase, other clinical trials (e.g., screening, prevention, diagnostic, and quality-of-life trials) may not be labelled this way.

### Use of Placebos

The use of placebos as comparison or “control” interventions in cancer treatment trials is rare. If a placebo is used by itself, it is because no standard treatment exists. In this case, a trial would compare the effects of a new treatment with the effects of a placebo. More often, however, placebos are given along with a standard treatment. For example, a trial might compare the effects of a standard treatment plus a new treatment with the effects of the same standard treatment plus a placebo.

### Possible benefits of taking part in a clinical trial

The benefits of participating in a clinical trial include the following:

- Trial participants have access to promising new interventions that are generally not available outside of a clinical trial.
- The intervention being studied may be more effective than standard therapy. If it is more effective, trial participants may be the first to benefit from it.
- Trial participants receive regular and careful medical attention from a research team that includes doctors, nurses, and other health professionals.
- The results of the trial may help other people who need cancer treatment in the future.
- Trial participants are helping scientists learn more about cancer (e.g., how it grows, how it acts, and what influences its growth and spread).

### Potential harms associated with taking part in a clinical trial

The potential harms of participating in a clinical trial include the following:

- The new intervention being studied may not be better than standard therapy, or it may have harmful side effects that doctors do not expect or that are worse than those associated with standard therapy.
- Trial participants may be required to make more visits to the doctor than they would if they were not in a clinical trial and/or may need to travel farther for those visits.

#### Correlative research studies, and how they are related to clinical trials

In addition to answering questions about the effectiveness of new interventions, clinical trials provide the opportunity for additional research. These additional research studies, called correlative or ancillary studies, may use blood, tumour, or other tissue specimens (also known as 'biospecimens') obtained from trial participants before, during, or after treatment. For example, the molecular characteristics of tumour specimens collected during a trial might be analysed to see if there is a relationship between the presence of a certain gene mutation or the amount of a specific protein and how trial participants responded to the treatment they received. Information obtained from these types of studies could lead to more accurate predictions about how individual patients will respond to certain cancer treatments, improved ways of finding cancer earlier, new methods of identifying people who have an increased risk of cancer, and new approaches to try to prevent cancer.

Clinical trial participants must give their permission before biospecimens obtained from them can be used for research purposes.

#### When a clinical trial is over

After a clinical trial is completed, the researchers look carefully at the data collected during the trial to understand the meaning of the findings and to plan further research. After a phase I or phase II trial, the researchers decide whether or not to move on to the next phase or stop testing the intervention because it was not safe or effective. When a phase III trial is completed, the researchers analyse the data to determine whether the results have medical importance and, if so, whether the tested intervention could become the new standard of care.

The results of clinical trials are often published in peer-reviewed scientific journals. Peer review is a process by which cancer research experts not associated with a trial review the study report before it is published to make sure that the data are sound, the data analysis was performed correctly, and the conclusions are appropriate. If the results are particularly important, they may be reported by the media and discussed at a scientific meeting and by patient advocacy groups before they are published in a journal. Once a new intervention has proven safe and effective in a clinical trial, it may become a new standard of care.

(National Cancer Institute).

#### **Medical Disclaimer**

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## Sources and References

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<http://www.cancer.org/cancer/oralcavityandoropharyngealcancer/detailedguide/oral-cavity-and-oropharyngeal-cancer-treating-by-stage>

### Cancer Research UK

<http://www.cancerresearchuk.org/about-cancer/type/mouth-cancer/treatment/surgery/types-of-mouth-cancer-operations>

### Chemiluminescence

[https://www.google.co.za/search?q=chemiluminescent+light&source=lnms&tbm=isch&sa=X&ei=LpX7UajlLcOZhQfh\\_YCICg&sqi=2&ved=0CAcQ\\_AUoAQ&biw=1366&bih=614#facrc=\\_&imgdii=\\_&imgrc=tDel2gOrXaVj4M%3A%3BEmNr4YZekGhutM%3Bhttp%253A%252F%252F2F67026%252Fwy%252Fimages%252F0106zila%252520062.jpg%3Bhttp%253A%252F%252Fwww.twincitiesdentalstudio.com%252Fvizilite%25252C2%2525AE-plus%252F%3B3504%3B2336](https://www.google.co.za/search?q=chemiluminescent+light&source=lnms&tbm=isch&sa=X&ei=LpX7UajlLcOZhQfh_YCICg&sqi=2&ved=0CAcQ_AUoAQ&biw=1366&bih=614#facrc=_&imgdii=_&imgrc=tDel2gOrXaVj4M%3A%3BEmNr4YZekGhutM%3Bhttp%253A%252F%252F2F67026%252Fwy%252Fimages%252F0106zila%252520062.jpg%3Bhttp%253A%252F%252Fwww.twincitiesdentalstudio.com%252Fvizilite%25252C2%2525AE-plus%252F%3B3504%3B2336)

### E-How

[http://www.ehow.com/about\\_4706811\\_beginning-stages-gum-cancer.html](http://www.ehow.com/about_4706811_beginning-stages-gum-cancer.html)

### Erythroplakia

[https://www.google.co.za/search?q=erythroplakia+pictures&source=lnms&tbm=isch&sa=X&ei=tWb7UcLzCsK4hAffq4DADQ&ved=0CAcQ\\_AUoAQ&biw=1366&bih=614#facrc=\\_&imgdii=\\_&imgrc=QbRcn1gqr0XrRM%3A%3Bi86yGdMlesmROM%3Bhttp%253A%252F%252Fwww.rborl.org.br%252Fconteudo%252Facervo%252Fimages%252F75-02-21-fig01.jpg%3Bhttp%253A%252F%252Fwww.rborl.org.br%252Fconteudo%252Facervo%252Fprint\\_acervo\\_english.asp%253Fid%253D3823%3B350%3B271](https://www.google.co.za/search?q=erythroplakia+pictures&source=lnms&tbm=isch&sa=X&ei=tWb7UcLzCsK4hAffq4DADQ&ved=0CAcQ_AUoAQ&biw=1366&bih=614#facrc=_&imgdii=_&imgrc=QbRcn1gqr0XrRM%3A%3Bi86yGdMlesmROM%3Bhttp%253A%252F%252Fwww.rborl.org.br%252Fconteudo%252Facervo%252Fimages%252F75-02-21-fig01.jpg%3Bhttp%253A%252F%252Fwww.rborl.org.br%252Fconteudo%252Facervo%252Fprint_acervo_english.asp%253Fid%253D3823%3B350%3B271)

### Gums

[http://medical-dictionary.thefreedictionary.com/Gum+\(anatomy\)](http://medical-dictionary.thefreedictionary.com/Gum+(anatomy))

### Leukoplakia

[https://www.google.co.za/search?q=leukoplakia+pictures&source=lnms&tbm=isch&sa=X&ei=gmf7UYTmA86zhAeg7IGQBw&sqi=2&ved=0CAcQ\\_AUoAQ&biw=1366&bih=614#facrc=\\_&imgdii=\\_&imgrc=9Yivy52EL3rpvM%3A%3BvzRYyOn17bTivM%3Bhttp%253A%252F%252F1.bp.blogspot.com%252F-iC-sxcZFeBg%252FThsNMSFsqXl%252FAAAAAAAAAAHg%252FHWthu-zCg1A%252Fs320%252Fleukoplakia%252Bof%252Bgingiva.jpg%3Bhttp%253A%252F%252Fdentallecnotes.blogspot.com%252F2011%252F07%252Fleukoplakia-is-most-common-premalignant.html%3B780%3B503](https://www.google.co.za/search?q=leukoplakia+pictures&source=lnms&tbm=isch&sa=X&ei=gmf7UYTmA86zhAeg7IGQBw&sqi=2&ved=0CAcQ_AUoAQ&biw=1366&bih=614#facrc=_&imgdii=_&imgrc=9Yivy52EL3rpvM%3A%3BvzRYyOn17bTivM%3Bhttp%253A%252F%252F1.bp.blogspot.com%252F-iC-sxcZFeBg%252FThsNMSFsqXl%252FAAAAAAAAAAHg%252FHWthu-zCg1A%252Fs320%252Fleukoplakia%252Bof%252Bgingiva.jpg%3Bhttp%253A%252F%252Fdentallecnotes.blogspot.com%252F2011%252F07%252Fleukoplakia-is-most-common-premalignant.html%3B780%3B503)

### MD Anderson Cancer Center

<http://www.mdanderson.org/patient-and-cancer-information/cancer-information/cancer-types/oral-cancer/diagnosis/index.html>

### MedicineNet.Com

[http://www.medicinenet.com/oral\\_cancer/page3.htm#oral\\_cancer\\_whos\\_at\\_risk](http://www.medicinenet.com/oral_cancer/page3.htm#oral_cancer_whos_at_risk)

### National Cancer Institute

<http://www.cancer.gov/clinicaltrials/learningabout/what-are-clinical-trials>

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**Oral Cancer Foundation**

<http://www.oralcancerfoundation.org/treatment/>

**Prenhall**

<http://wps.prenhall.com/wps/media/objects/2976/3047536/MC20.pdf>

**Right Diagnosis**

[http://www.rightdiagnosis.com/g/gum\\_cancer/](http://www.rightdiagnosis.com/g/gum_cancer/)