Cancer Association of South Africa (CANSA)

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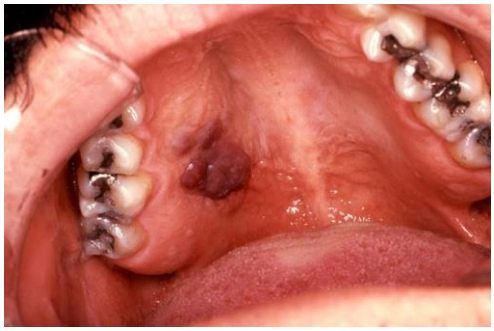
Fact Sheet
on
Cancer of the Palate

Introduction

Mouth cancers, of which cancer of the palate is one, most commonly begin in the flat, thin cells (squamous cells) that line one's lips and the inside of one's mouth. Most oral cancers are squamous cell carcinomas. It is not clear what causes the mutations in squamous cells that lead to mouth cancer, but doctors have identified various factors that may increase the risk of mouth cancer.



[Picture Credit: Cancer of the Palate]

Mouth cancer is a general term that applies to cancers that occur on the lips and throughout the mouth.

More-specific terms for these types of cancer include:

- Cancer that affects in the inside portion of the cheeks (buccal mucosa cancer)
- Floor of mouth cancer
- Gum cancer
- Lip cancer
- Roof of mouth (hard palate) cancer
- Salivary gland cancer
- Tongue cancer

(Mayo Clinic).

Cancer of the Palate

Cancer of the palate usually occurs when the squamous cells in the mouth area divide in an uncontrolled manner.

The palate is commonly called the roof of the mouth. It is divided into two parts: the bony hard palate in the front, and the fleshy soft palate (called the velum) in the back of the mouth. The hard palate is part of the oral cavity and the soft palate is part of the oropharynx.

The hard palate creates a barrier between the mouth and the nasal cavity. A natural opening in the palate for nerves and blood vessels (near the third molar teeth) can create a passageway for a tumour to spread into the nasal cavity.

The soft palate closes the nasal passage during swallowing so food does not enter the nose. It also helps create speech sounds. If the palate does not function correctly during speech, air escapes through the nose, and the speech has a nasal sound. During a sneeze, the soft palate closes the nasal passage to protect it. Substances in the sneeze are thrown out into the mouth.
(Cedars-Sinai).

Incidence of Cancer of the Palate
The National Cancer Registry (2012) does not provide information regarding the incidence of Cancer of the Palate. It, however, provides information about the incidence of cancer of the mouth.

According to the National Cancer Registry (2012) the following number of cancer of the mouth 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	406	1:346	1,10%
Asian males	16	1:331	1,87%
Black males	217	1:423	1,86%
Coloured males	59	1:227	1,35%
White males	114	1:256	0,57%

Group - Females 2012	Actual No of Cases	Estimated Lifetime Risk	Percentage of All Cancers
All females	198	1:1 009	0,53%
Asian females	12	1:637	1,10%
Black females	75	1:2 080	0,45%
Coloured females	40	1:338	0,96%
White females	71	1:542	0,45%

The frequency of histologically diagnosed cases of cancer of the mouth 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	1	4	9	53	125	198	62	16
Asian males	0	1	0	1	3	5	1	2
Black males	1	3	7	21	74	58	29	6
Coloured males	0	0	0	11	13	20	7	4
White males	0	0	2	13	32	36	21	4

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	3	1	6	13	46	58	38	29
Asian females	0	0	0	0	2	5	2	1
Black females	1	1	3	8	14	16	11	13
Coloured females	0	0	0	0	13	16	7	1
White females	1	0	3	3	13	17	16	10

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.

Signs and Symptoms of Cancer in the Palate and Mouth
Mouth cancer symptoms can include:

- Sores or lesions in the mouth that do not heal and bleed easily for no reason
- Red or white patches on the mouth's surface
- Constant mouth pain that does not go away
- A lump or mass in the mouth
- Constant ear pain
- Difficulty chewing, swallowing, talking or moving one's jaw
- Numbness in any area of the mouth
- Swelling in the mouth that causes dentures to fit poorly
- Weight loss as a result of difficulty eating
- Constant bad breath
- Loose teeth
- Dentures no longer fit
- Difficulty in swallowing
- Changes in speech
- A lump in the neck
- Inability to open the jaw

(Mouth Cancer Symptoms; St Lawrence Dentistry).

Causes and Risk Factors for Cancer of the Palate and Mouth
By far the most common factor contributing to most head and neck cancers is using tobacco, particularly smoking it. Drinking too much alcohol also adds to the risk of developing head and neck cancers.

Major factors that increase the chance of developing palate cancer include:

- Smoking or tobacco use is one of the main causes of palate cancer. It is estimated that up to 90% of oral cancers are caused by cigarette, pipe or cigar smoking
- Those who chew tobacco and snuff are also at risk of developing this cancer
- Alcoholic beverages also contribute in the development of palate cancer
- Leukoplakia is a condition that causes white patches in the mouth is also said to be a risk factor for this cancer
- Reverse smoking is also a risk factor. This type of smoking is where the lit end of the cigarette is placed inside the mouth, which generates intense heat inside the mouth
- Heavy alcohol use
- Excessive sun exposure to one's lips
- The sexually transmitted virus - human papillomavirus (HPV)
- Exposure to radiation in the past. Being exposed to radiation through previous treatment for another disease, certain working conditions or even a natural disaster can increase the chances of some cancers
- Genetic factors. This is important in all cancers, and the details are still being determined
- Spicy foods.
- Lack of some vitamins
- Poor oral hygiene might also be associated with oropharyngeal cancers

In the early stages, cancer of the palate may not manifest any symptoms and can look like a harmless sore. If a mass growth is observed in one's mouth, it is best to have a dentist or

medical practitioner examine it, because early detection of the cancer increases and improves the survival rate. If one regularly visits one's dentist, the dentist will be able to notice any suspicious changes in one's mouth.
(Head and Neck Cancer Guide; St Lawrence Dentistry; Mayo Clinic).

Staging of Cancer of the Palate
Staging is the process of finding out how far a cancer has spread. The outlook (prognosis) for people with cancer depends, to a large extent, on the cancer's stage. The stage of oral cavity and oropharyngeal cancers is one of the most important factors in choosing treatment.

The TNM Staging System
A staging system is a standard way for doctors to describe and summarize how far a patient's cancer has spread. The most common system used to describe the extent of oral cavity and oropharyngeal cancers is the TNM system of the American Joint Committee on Cancer (AJCC). The TNM system for staging describes 3 key pieces of information:

- **T** indicates the size of the main (primary) **tumour** and which, if any, tissues of the oral cavity or oropharynx it has spread to.
- **N** describes the extent of spread to nearby (regional) lymph **nodes**. Lymph nodes are small bean-shaped collections of immune system cells to which cancers often spread first.
- **M** indicates whether the cancer has spread (**metastasised**) to other organs of the body. (The most common site of spread is to the lungs. The next most common sites are the liver and bones.)

  - Numbers or letters appear after T, N, and M to provide details about each of these factors:
    The numbers 0 through 4 indicate increasing severity.
    The letter X means "cannot be assessed" because the information is not available.

T categories for cancers of the lip, oral cavity, and oropharynx

TX: Primary tumour cannot be assessed; information not known
T0: No evidence of primary tumour
Tis: Carcinoma in situ. This means the cancer is still within the epithelium (the top layer of cells lining the oral cavity and oropharynx) and has not yet grown into deeper layers.
T1: Tumour is 2 cm (about ¾ inch) across or smaller
T2: Tumour is larger than 2 cm across, but smaller than 4 cm (about 1 ½ inch)
T3: Tumour is larger than 4 cm across. For cancers of the oropharynx, T3 also includes tumours that are growing into the epiglottis.
T4a: Tumour is growing into nearby structures. This is known as *moderately advanced local disease*.

- For oral cavity cancers: the tumour is growing into nearby structures, such as the bones of the jaw or face, deep muscle of the tongue, skin of the face, or the maxillary sinus.
- For lip cancers: the tumour is growing into nearby bone, the inferior alveolar nerve (the nerve to the jawbone), the floor of the mouth, or the skin of the chin or nose.

- For oropharyngeal cancers: the tumour is growing into the larynx (voice box), the tongue muscle, or bones such as the medial pterygoid, the hard palate, or the jaw.

T4b: The tumour has grown through nearby structures and into deeper areas or tissues. This is known as *very advanced local disease*. Any of the following may be true:

- The tumour is growing into other bones, such as the pterygoid plates and/or the skull base (for any oral cavity or oropharyngeal cancer).
- The tumour surrounds the internal carotid artery (for any oral cavity or oropharyngeal cancer).
- For lip and oral cavity cancers: the tumour is growing into an area called the *masticator space*.
- For oropharyngeal cancers: the tumour is growing into a muscle called the *lateral pterygoid muscle*.
- For oropharyngeal cancers: the tumour is growing into the nasopharynx (the area of the throat that is behind the nose).

N categories

NX: Nearby lymph nodes cannot be assessed; information not known

N0: The cancer has not spread to nearby lymph nodes

N1: The cancer has spread to one lymph node on the same side of the head or neck as the primary tumour; this lymph node is no more than 3 cm (about 1¼ inch) across

N2 includes 3 subgroups:

N2a: The cancer has spread to one lymph node on the same side as the primary tumour; the lymph node is larger than 3 cm across but no larger than 6 cm (about 2 ½ inches)

N2b: The cancer has spread to 2 or more lymph nodes on the same side as the primary tumour, but none are larger than 6 cm across

N2c: The cancer has spread to one or more lymph nodes on both sides of the neck or on the side opposite the primary tumour, but none are larger than 6 cm across

N3: The cancer has spread to a lymph node that is larger than 6 cm across

M categories

M0: No distant spread

M1: The cancer has spread to distant sites outside the head and neck region (for example, the lungs)

Stage grouping

Once the T, N, and M categories have been assigned, this information is combined by a process called *stage grouping* to assign an overall stage of 0, I, II, III, or IV. Stage IV is further divided into A, B, and C.

Stage 0

Tis, N0, M0: Carcinoma in situ. The cancer is only growing in the epithelium, the outer layer of oral or oropharyngeal tissue (Tis). It has not yet grown into a deeper layer or spread to nearby structures, lymph nodes (N0), or distant sites (M0).

Stage I
T1, N0, M0: The tumour is 2 cm (about ¾ inch) across or smaller (T1) and has not spread to nearby structures, lymph nodes (N0), or distant sites (M0).

Stage II
T2, N0, M0: The tumour is larger than 2 cm across but smaller than 4 cm (T2) and has not spread to nearby structures, lymph nodes (N0), or distant sites (M0).

Stage III
One of the following applies:
T3, N0, M0: The tumour is larger than 4 cm across (T3), but it hasn't grown into nearby structures or spread to the lymph nodes (N0) or distant sites (M0).

OR

T1 to T3, N1, M0: The tumour is any size and hasn't grown into nearby structures (T1 to T3). It has spread to one lymph node on the same side of the head or neck, which is no larger than 3 cm across (N1). The cancer hasn't spread to distant sites (M0).

Stage IVA
One of the following applies:
T4a, N0 or N1, M0: The tumour is growing into nearby structures (T4a). It can be any size. It has either not spread to the lymph nodes (N0) or has spread to one lymph node on the same side of the head or neck, which is no larger than 3 cm across (N1). The cancer hasn't spread to distant sites (M0).

OR

T1 to T4a, N2, M0: The tumour is any size and may or may not grow into nearby structures (T1 to T4a). It has not spread to distant sites (M0). It has spread to one of the following:
1. One lymph node one the same side of the head and neck that is between 3 and 6 cm across (N2a), or
2. One lymph node on the opposite side of the head and neck that is no more than 6 cm across (N2b), or
3. 2 or more lymph nodes, all of which are no more than 6 cm across. The lymph nodes can be on any side of the neck (N2c)

Stage IVB
One of the following applies:
T4b, any N, M0: The tumour is growing into deeper areas and/or tissues (very advanced local disease - T4b). It may (or may not) have spread to lymph nodes (any N). It has not spread to distant sites (M0).

OR

Any T, N3, M0: The tumour is any size and it may or may not have grown into other structures (any T). It has spread to one or more lymph nodes larger than 6 cm across (N3), but it hasn't spread to distant sites (M0).

Stage IVC
Any T, Any N, M1: The tumour is any size (any T), and it may or may not have spread to lymph nodes (any N). It has spread to distant sites (M1), most commonly the lungs.

Recurrent (Relapsed) Cancer
This is not an actual stage in the TNM system. Recurrent (relapsed) disease means that the cancer has come back (recurred) after treatment. Recurrent oral cavity or oropharyngeal cancer may return in the mouth or throat (local recurrence), in nearby lymph nodes (regional recurrence) or in another part of the body, such as the lungs (distant recurrence).

Talk with a doctor in case of any questions about the stage of the cancer or how it affects treatment.
(American Cancer Society).

Treatment of Cancer of the Palate
Treatment will be discussed under cancer of the hard palate and cancer of the soft palate:

Treatment for soft palate cancer depends on many factors, such as the size and location of your cancer, your overall health and your preferences. Treatment options may include:

Treatment of Soft Palate Cancer:
Surgery**.** During surgery for soft palate cancer, skilled surgeons trained in removing throat cancers will work to remove your cancer.

If the cancer is small, it may be removed during a short operation that won't require a hospital stay. Larger cancers may require more-extensive operations. When the cancer has spread to the neck lymph nodes, lymph node removal may be necessary.
Mayo Clinic's innovative surgical techniques can remove the cancer and provide the best possible function. For example, in transoral robotic surgery, which is less invasive than conventional surgery, skilled surgeons use special instruments to view the soft palate through the mouth and nose.

Radiation therapy**.** Radiation therapy can be used alone or with chemotherapy or surgery to treat soft palate cancers of all stages.

Highly skilled radiation oncologists provide state-of-the-art radiation therapy at Mayo Clinic, including intensity-modulated radiation therapy, 3-D conformal radiation therapy, stereotactic radiosurgery, brachytherapy, and small field conformal radiation therapy.

Chemotherapy**.** Experienced medical oncologists prescribe chemotherapy — which can be administered through a vein, by mouth or both — to treat soft palate cancer that has spread beyond the throat. Chemotherapy may also be combined with radiation therapy.

Reconstructive surgery**.** Depending on the location and spread of the cancer, reconstructive surgery may be necessary. Experienced surgeons work to improve appearance and function through reconstruction of the soft palate to restore speech and swallowing function.

Rehabilitative services**.** To assist in recovery, health care providers offer many rehabilitative services like speech therapy, dietary counselling and physical and occupational therapy. In addition, they can help people who want to stop using tobacco (Mayo Clinic).

Treatment of Hard Palate Cancer:
Surgery. Surgery is the preferred treatment for cancer of the hard palate. The bone closest to the tumour often contains cancer cells and part of it may also need to be removed. If the tumour is small, the excised area can easily be closed after surgery.

If the tumour is large, the excised area cannot be closed and a prosthetic device is needed to cover the opening in the roof of the mouth. The prosthesis looks similar to a denture plate. If the lymph nodes in the neck are affected, a neck dissection may be needed to remove the nodes.

Radiation Therapy. Radiation therapy can be prescribed before surgery, after surgery, or sometimes as the only treatment. Radiation uses high-energy X-rays, electron beams, or radioactive isotopes to destroy cancer cells.

Intensity-Modulated Radiation Therapy (IMRT) uses a computer to deliver precise doses of radiation to a tumour or an area of a tumour. This minimizes radiation exposure to the surrounding normal tissue. IMRT allows the use of more effective radiation doses with fewer side effects than conventional radiotherapy techniques.

Radiation therapy, including IMRT, stops cancer cells from dividing. The growth of the tumour is slowed. Radiotherapy also destroys cancer cells and can shrink or eliminate tumours.

Radiation therapy involves 5-6 weeks of daily treatments.

Chemotherapy. Medical oncologists administer chemotherapy if the cancer has spread to lymph nodes or other organs. The medicine circulates in the blood and disrupts the growth of the cancer cells. Chemotherapy medications are taken by mouth or given through a vein for several months.

Chemotherapy is prescribed for different reasons:

- together with radiotherapy as an alternative to surgery (called chemoradiation)
- after surgery to decrease the risk of the cancer returning
- to slow the growth of a tumour and control symptoms when the cancer cannot be cured (palliative treatment)

Radiation Therapy and Chemotherapy. A combination of radiation therapy and chemotherapy (chemoradiation) is an effective treatment.

Radiation therapy used alone or with chemotherapy is the primary treatment for moderate or advanced cancers in order to preserve the soft palate and its function.

Radiotherapy can be combined with chemotherapy and surgery.
(Cedars-Sinai).

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).

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