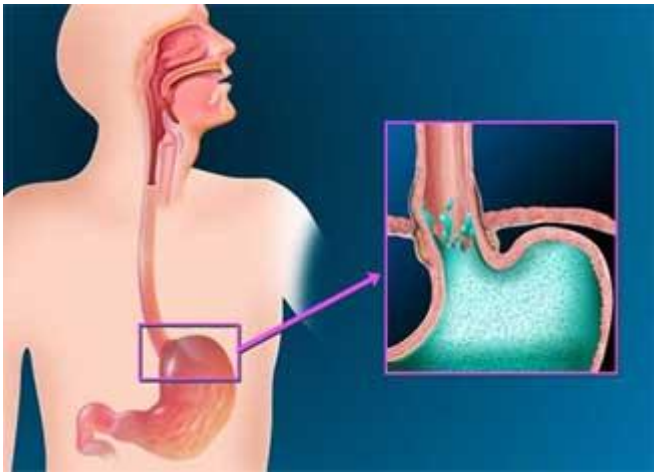
Cancer Association of South Africa (CANSA)

Research • Educate • Support

Fact Sheet on Barrett's Oesophagus

Introduction

Barrett's Oesophagus is a disorder in which the lining of the oesophagus is damaged. This damage occurs when parts of the oesophageal lining are repeatedly exposed to stomach acid, and are replaced by tissue that is similar to what is found in the intestine. This process is called intestinal metaplasia.



[Picture Credit: Barrett's Oesophagus]

The cells in the lining of the oesophagus and the stomach have different functions, and are different types of cells. Also, their appearance is very different, making it easy for a physician to tell them apart when examining the oesophagus and stomach. At the end of the oesophagus, there is an area that marks the border between the cells of the oesophagus and the cells of the stomach. With Barrett's Oesophagus, abnormal intestinal-like cells develop above this border.

Understanding how the Oesophagus and Stomach Functions

When food is ingested, it passes down the gullet (oesophagus) into the stomach. Cells in the lining of the stomach make acid and other chemicals which help to digest the food. Stomach cells also make a thick liquid (mucus) which protects them from damage caused by the acid. The cells on the inside lining of the oesophagus, however, are different and have little protection from the acid produced in the stomach.

There is a circular band of muscle (a sphincter) at the junction between the oesophagus and stomach. This relaxes to allow food down, but normally tightens up and stops food and acid leaking back up (refluxing) into the oesophagus. So, the sphincter acts like a valve and protects the oesophagus in unaffected individuals from being exposed to stomach acid. (Patient.co.uk).

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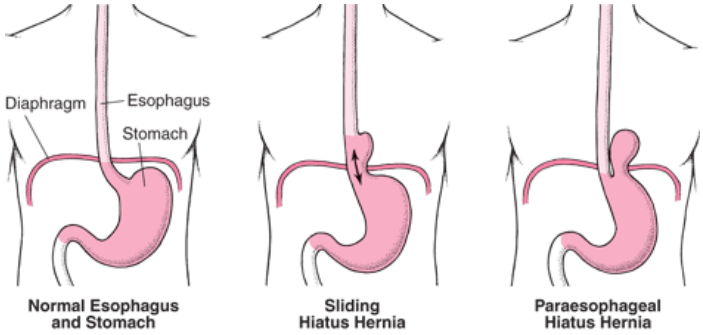
Causes and Risks for Barrett's Oesophagus
The following are the two main causes of Barrett's Oesophagus:

Acid Reflux - this happens when the valve at the lower end of the oesophagus is weak and allows stomach contents to splash up into the oesophagus. Reflux of acid is very common and many people have symptoms at some point in their lives.

Certain factors can make people more likely to have reflux. These include:

- being overweight
- smoking
- excessive alcohol consumption
- eating spicy, acidic, or fatty foods.

Acid reflux can also be caused by a hiatus hernia. A hiatus hernia is when a small piece of the stomach is displaced and pokes up through the diaphragm. The diaphragm is the sheet of muscle that divides the tummy area from the chest.



[Picture Credit: Hiatus Hernia]

GORD (gastro-oesophageal reflux disease) - this is when stomach acid irritates the oesophagus. The stomach produces acid to help digest food. While the stomach is lined by tissue that is resistant to acid, the oesophagus is not. In some people, the acid can inflame and irritate the oesophagus, causing pain and heartburn. This is often referred to as gastro-oesophageal reflux disease (GORD) or reflux oesophagitis (inflammation of the oesophagus).

Not everyone who has acid reflux will develop Barrett's Oesophagus. Up to 1 in 10 people with acid reflux (10%) will develop Barrett's Oesophagus. It is more likely to happen in people who have had severe reflux for many years. It is also more likely in people over 50, and in men.
(MacMillan Cancer Support).

The risk of having acid reflux is higher if one:

- is overweight
- smokes tobacco
- drinks large amounts of alcohol
- eats spicy or fatty foods
- is a white male

Researchers are currently looking into the causes of Barrett's Oesophagus including:

- Why some people develop it and others do not
- Whether there is an increased risk of developing it if someone in the family has it
- Whether there is a link between being very overweight (obesity) and developing Barrett's Oesophagus

(Cancer Research UK).

The Risk of Oesophageal Cancer from Barrett's Oesophagus

It is known that Barrett's Oesophagus can increase one's risk for cancer of the oesophagus. Barrett's oesophagus is most likely to be diagnosed in people who have a long history of burning indigestion. So it is important to see one's doctor if one has had burning indigestion for any extended period of time.

If a person has Barrett's Oesophagus he/she will need to see a doctor regularly. They will also need to have regular examinations of the inside of the oesophagus (food pipe). These examinations are called endoscopies. These examinations do not prevent oesophageal cancer, but should help to pick it up early on when there is a better chance for successful treatment (Cancer Research UK).

Incidence of Oesophageal Cancer in South Africa

According to the National Cancer Registry (2011) the following number of oesophageal cancer cases was histologically diagnosed in South Africa during 2011:

Group - Males 2011	No of Cases	Lifetime Risk	Percentage of All Cancers
All males	864	1:150	2,70%
Asian males	12	1:467	1,99%
Black males	598	1:138	3,20%
Coloured males	109	1:100	2,83%
White males	145	1:212	0,81%

Group - Females 2011	No of Cases	Lifetime Risk	Percentage of All Cancers
All females	651	1:275	2,04%
Asian females	9	1:1 084	1,41%
Black females	511	1:236	3,71%
Coloured females	72	1:183	1,92%
White females	59	1:773	0,43%

The frequency of histologically diagnosed cases of oesophageal cancer in South Africa for 2011 was as follows (National Cancer Registry, 2011):

Group - Males 2011	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	19	111	267	259	132	48
Asian males	0	0	0	1	2	3	4	1
Black males	0	0	14	79	197	174	78	31
Coloured males	0	0	2	14	25	38	23	5
White males	0	0	3	17	43	44	27	11

Group - Females 2011	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	3	10	57	166	174	142	71
Asian females	0	2	0	0	2	2	0	2
Black females	0	o	10	47	131	140	107	51
Coloured females	0	1	0	5	23	16	23	3
White females	0	0	0	5	10	16	12	15

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 Barrett's Oesophagus

The exact causes of Barrett's Oesophagus are unknown, but it is thought to be caused in part by the same factors that cause GORD. Although people who do not have heartburn can have Barrett's Oesophagus, it is found about three to five times more often in people with this condition. Indeed 10-20% of people with chronic GORD will develop Barrett's Oesophagus.

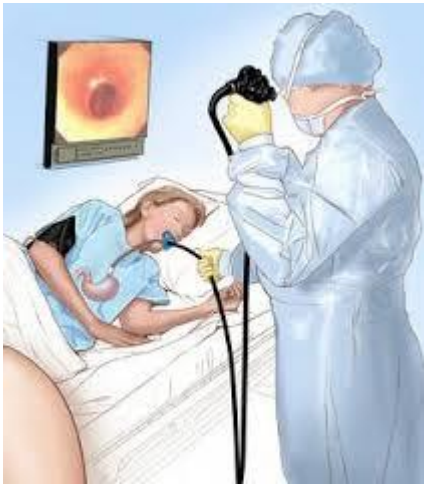
The muscular layers of the oesophagus are normally pinched together at both the upper and lower ends by muscles called sphincters. When a person swallows, the sphincters relax automatically to allow food or drink to pass from the mouth and into the stomach. The muscles then close rapidly to prevent the swallowed food or drink from leaking out of the stomach back into the oesophagus or into the mouth. These muscles make it possible to swallow while lying down or even upside-down. When people belch to release swallowed air or gas from carbonated beverages, the sphincters relax and small amounts of food or drink may come back up briefly; this condition is called reflux. The oesophagus quickly squeezes the material back into the stomach, and this is considered normal.

When a person experiences this regularly, especially when not trying to belch, then it is considered a medical problem or disease. The stomach produces acid and enzymes and when this mixture refluxes into the oesophagus frequently, it may produce symptoms. These symptoms, often called acid reflux, are usually described by people as heartburn, indigestion or 'gas'. The symptoms usually consist of a burning sensation below and behind part of the breastbone or sternum. Most people have experienced these symptoms at least once, typically as a result of overeating. Other situations that provoke GORD symptoms include obesity, eating certain types of food and pregnancy. In most people, GORD symptoms may last only a short time and require no treatment. However, the more persistent and numerous these symptoms become, it is recommended that the person consult a doctor. These symptoms, if continuing for some time without relief from 'over-the-counter' antacid agents, can contribute to the development of GORD and eventually Barrett's Oesophagus.

The average age of patients diagnosed with Barrett's Oesophagus is 50 to 60; diagnosis of this condition diminishes the younger the person is, as Barrett's Oesophagus develops over a longer time than GORD. Indeed it is uncommon for Barrett's Oesophagus to be diagnosed in children. It is about twice as common in men as in women, and much more common in white men than in men of other racial background.
(Centre for Digestive Diseases).

Diagnosis of Barrett's Oesophagus

To make a diagnosis of Barrett's Oesophagus an endoscopy of the oesophagus must be done. In this procedure a tube is inserted through the mouth and down the oesophagus to view and biopsy the lining of the oesophagus.



[Picture Credit: Endoscopy]

The two requirements to make a diagnosis are:

During endoscopy of the lower oesophagus, an abnormal pink lining is seen as replacing the normal whitish lining of the oesophagus. This abnormal lining is seen to extend a short distance up the oesophagus from the gastro-

oesophageal junction, which is where the oesophagus joins the stomach.

Biopsy (tissue sampling) of this abnormal lining shows (under the microscope) the presence of intestinal or stomach-like cells called columnar cells.
(WebMD).

Management of Barrett's Oesophagus
Once Barrett's Oesophagus has been identified, patients should undergo periodic surveillance endoscopy to identify histologic markers for increased cancer risk (dysplasia) or cancer that is at an earlier stage and is amenable to therapy. Dysplasia is the best histologic marker for cancer risk.

The management options for high-grade dysplasia include the following:
- Surveillance endoscopy, with intensive biopsy at 3-month intervals until cancer is detected
- Endoscopic ablation: In most major medical centres, ablation is first-line therapy
- Surgical resection: While studies have shown surgery to be efficacious in the control of GORD symptoms, no good evidence indicates that surgical therapy provides regression in Barrett's Oesophagus

Pharmacologic treatment for Barrett's Oesophagus should be the same as that for GORD, although most authorities agree that treatment should employ a proton pump inhibitor (PPI) instead of an H2-receptor antagonist, due to the relative acid insensitivity of patients with Barrett's Oesophagus. While PPIs have been found to be better than H2-receptor antagonists at reducing gastric acid secretion, the evidence as to whether PPIs induce regression of Barrett's Oesophagus remains inconclusive.

Diet:
The diet for patients with Barrett's Oesophagus is the same as that recommended for patients with GORD.

Patients should avoid the following:
- Fried or fatty foods
- Chocolate
- Peppermint
- Alcohol
- Coffee
- Carbonated beverages
- Citrus fruits or juices
- Tomato sauce
- Ketchup
- Mustard
- Vinegar
- Aspirin and other nonsteroidal anti-inflammatory drugs (NSAIDs)

(Medscape).

Treatment of Barrett's Oesophagus
Treatment for Barrett's Oesophagus depends on the degree of dysplasia found in the oesophagus cells and the person's overall health.

<u>No dysplasia or low-grade dysplasia</u>
The doctor will likely recommend:

- Periodic endoscopy to monitor the cells in your oesophagus. If your biopsies show no dysplasia, you'll probably have a follow-up endoscopy in one year and then every three years if no changes occur. If low-grade dysplasia is found, your doctor may recommend another endoscopy in six months or a year.
- Treatment for GORD. Medication and lifestyle changes can ease your signs and symptoms. Surgery to tighten the sphincter that controls the flow of stomach acid may be an option. Treating GORD doesn't treat the underlying Barrett's oesophagus but can help make it easier to detect dysplasia.

High-grade dysplasia

High-grade dysplasia is thought to be a precursor to oesophageal cancer. For this reason, the doctor may recommend:

- Endoscopic resection, which uses an endoscope to remove damaged cells.
- Radiofrequency ablation, which uses heat to remove abnormal oesophagus tissue. Radiofrequency ablation may be recommended after endoscopic resection.
- Cryotherapy, which uses an endoscope to apply a cold liquid or gas to abnormal cells in the oesophagus. The cells are allowed to warm up and then frozen again. The cycle of freezing and thawing damages the abnormal cells.
- Photodynamic therapy, which destroys abnormal cells by making them sensitive to light.
- Surgery in which the damaged part of the oesophagus is removed and the remaining portion is attached to the stomach.

If the patient has treatment other than surgery to remove the oesophagus, the doctor is likely to recommend medication to reduce acid and help the oesophagus heal.

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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