Cancer Association of South Africa (CANSA)

Research • Educate • Support

Fact Sheet
On
Cancer of the Heart

Introduction

The heart is one of the most important organs in the entire human body. It is really nothing more than a pump. It is composed of muscle which pumps blood throughout the body. It beats on average 72 times per minute throughout our lives. The heart pumps the blood, which carries all the vital materials which helps the human body function and removes the waste products that is not needed. For example, the brain requires oxygen and glucose, which, if not received continuously, will cause it to lose consciousness. Muscles need oxygen, glucose and amino acids, as well as the proper ratio of sodium, calcium and potassium salts in order to contract normally. The glands need sufficient supplies of raw materials from which to manufacture the specific secretions. If the heart ever ceases to pump blood, the body begins to shut down and after a very short period of time will die.

[Picture Credit: Heart]

The heart is essentially a muscle (a little larger than one's fist). Like any other muscle in the human body, it contracts and expands. Unlike skeletal muscles, however, the heart works on the 'All-or-Nothing Law'. That is, each time the heart contracts it does so with all its force. In skeletal muscles, the principle of 'gradation' is present.

The pumping of the heart is called the *Cardiac Cycle*, which occurs about 72 times per minute. This means that each cycle lasts about eight-tenths of a second. During this cycle the entire heart actually rests for about four-tenths of a second.
(World Invisible).

Anatomy and Physiology of the Heart

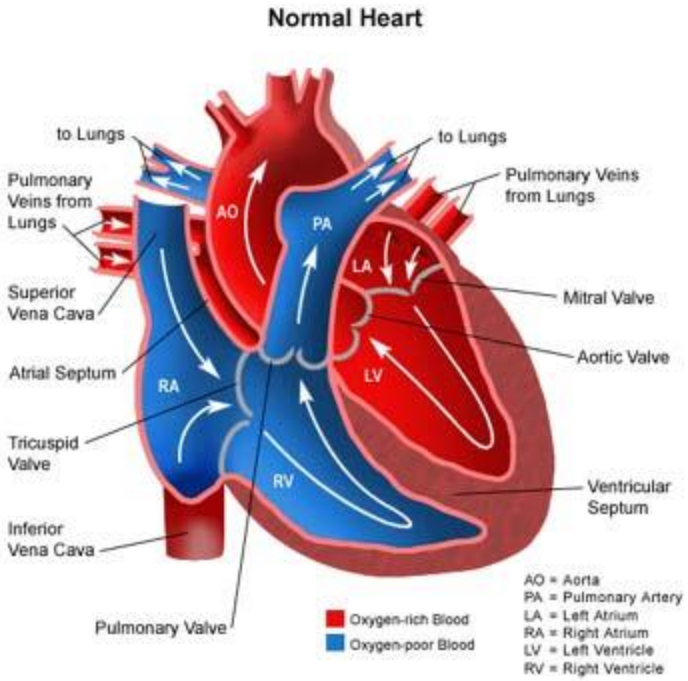
The wall of the heart consists of three layers:

- The *epicardium* is the visceral layer of the serous pericardium.

- The *myocardium* is the muscular part of the heart that consists of contracting cardiac muscle and noncontracting Purkinje fibers that conduct nerve impulses. Cardiac cells (cardiomyocytes) are found in this layer.

- The *endocardium* which is the thin, smooth, endothelial, inner lining of the heart, which is continuous with the inner lining of the blood vessels.

[Picture credit: Heart Anatomy].



The presence of a typical heart is found in all animals with a circulatory system as well as humans (vertebrates). The term *cardiac* (as used in cardiology) means 'related to the heart' and comes from the Greek καρδιά, *kardia*, for 'heart'. The vertebrate heart is principally composed of cardiac (heart) muscle and connective tissue. Cardiac muscle is involuntary striated muscle tissue (having the ability to contact and relax without external interference). This type of tissue is found only in the heart and is responsible for the ability of the heart to continuously pump blood. The average human heart, beating at 72 beats per minute, will beat approximately 2,5 billion times during an average 65 year lifespan. It weighs approximately 250 to 300 grams in females and 300 to 350 grams in males.

Incidence of Heart Cancer in South Africa

The National Cancer Register (2012) does not provide any statistics on the incidence of heart cancer in South Africa.

The Prevalence of Heart Cancer

Any cell in the body can become malignant and cause cancer. Cancer can, therefore, develop in any tissue within the body including the heart.

Cancer arises from mutations that take place within the deoxyribonucleic acid (DNA) of a particular cell. Cancerous cells usually undergo several mutations before it eventually becomes a deadly, invasive cancer. Most mutations occur when cells divide and replicate its DNA. The only manner in which a cell can propagate a mutation is during cell division when mutations are passed on to daughter cells (Scientific American).

When one considers the most common types of cancer one usually thinks of cancer of the breast, skin, colon and the like. Most of the cells in these tissues are continually replacing themselves. Breast cells, for example, are constantly affected by hormones and breast tissue is always growing and shrinking. The cells found in the colon are continually sloughing

off and being replaced as are the cells of the skin. As a result of the continuous cell division that takes place, there is an increased risk of mutations occurring because of the influence of carcinogens.

The heart, in contrast, does not get exposed to many carcinogens – only those carcinogens present in the blood. That, combined with the fact that the heart usually does not continue to grow once it is fully developed and the fact that its cells seldom replicate, is responsible that heart cancer is not often seen. A study of over 12 000 autopsies conducted in Hong Kong found only seven (7) tumours of the heart, most of which were benign (eHow). The research conducted by doctors from Hong Kong showed that the majority of the cases of these tumours were due to sarcoma (Cancer8). At the three Mayo Clinics (United States of America), on average, only one (1) case of heart cancer is seen a year (Mayo Clinic).

There are no statistics regarding cancer of the heart available for South Africa in the National Cancer Registry 2011.

Heart cancer (primary cardiac tumour) is cancer that arises in the heart. Cancerous (malignant) tumours that begin in the heart are most often sarcomas, a type of cancer that originates in the soft tissues of the body. The vast majority of heart tumours are noncancerous (benign). Heart cancer is extremely rare.

Although still rare, most cancers found in the heart have come from elsewhere in the body. Cancers that begin near the heart, such as lung cancer, can grow to involve the heart or the lining around the heart (pericardial sac). Or cancer can begin elsewhere in the body and spread to the heart through the bloodstream.

Cancers that may affect the heart include:

- breast cancer
- kidney cancer
- lung cancer
- leukaemia
- lymphoma; and
- melanoma

Cancer can affect the heart in other ways, as well. A rare type of cancer known as carcinoid tumour at times produces hormones that can damage heart valves.

Cancer treatments also can damage the heart. Cancer treatments linked to heart problems include several types of chemotherapy drugs, certain targeted therapy drugs, radiation therapy aimed near the heart, and hormone therapy. Some heart problems are detected during treatment, while others may not become apparent for many years after treatment. In many cases, the heart damage is reversible, though some types of heart damage can be permanent.
(Mayo Clinic).

Cancer of the Heart

Of tumours that start in the heart, most are not cancer – they are benign. But about 1 in 4 (25%) are cancers. Most commonly these are soft tissue sarcomas. Soft tissue connects,

supports, and surrounds the other structures and organs of the body. Angiosarcomas are a type of soft tissue sarcoma that grow from cells that make up the walls of blood vessels. (Cancer Research UK).

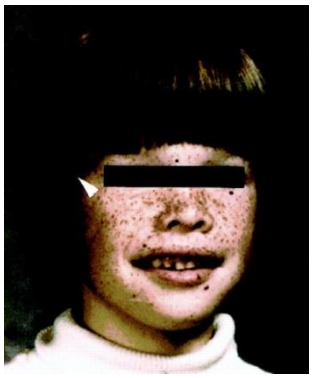
Causes of Cancer of the Heart

A small percentage of patients with cardiac tumours have a family history of the condition. Sometimes, the tumours can be part of another health condition, such as:

- NAME Syndrome - **Nevi**, meaning birthmarks or moles, **Atrial myxoma**, Myxoid neurofibromas, and Ephelides (freckles)

- LAMB Syndrome - **Lentigines**, **Atrial Myxoma**, and Blue **nevi**

- Carney Syndrome (or complex) - an autosomal dominant genetic syndrome associated with spotty pigmentation of the skin, endocrinopathy, and endocrine and nonendocrine tumours, including the following:



[Picture Credit: Carney Syndrome]

  - Myxomas of the skin, heart, breast, and other sites
  - Primary pigmented nodular adrenocortical disease
  - Psammomatous melanotic schwannomas
  - Growth hormone–producing pituitary adenomas
  - Testicular Sertoli-cell tumours
  - Possibly, other benign and malignant neoplasms and conditions, including tumours of the thyroid gland and ductal adenomas of the breast, as well as acromegaly due to somatomammotroph hyperplasia and adenomas not dependent on growth hormone–releasing hormone

Most often, the tumour develops without any of those conditions or family history. They are the result of cell overgrowth that either starts in the heart or moves to the heart (Cleveland Clinic).

Types of Heart Cancer

Heart cancer is an extremely rare form of cancer that is divided into primary tumours of the heart (tumours that originate in the heart tissue) and secondary tumours of the heart (tumours that originate outside the heart). Primary tumours of the heart are rare, and over 75 percent of primary cardiac tumours are benign (non-cancerous).

Most heart tumours are benign and include:

- myxoma - A myxoma is a rare, usually noncancerous, primary tumour (a new growth of tissue) of the heart. It is the most common of all benign heart tumours

- fibroma – A fibroma is a tumour composed mainly of fibrous or fully developed connective tissue

- rhabdomyoma – a rhabdomyoma is a benign (noncancerous) tumour derived from striated muscle; the cardiac form is considered to be a hamartoma and is often associated with tuberous sclerosis

- hamartoma - a benign (noncancerous) tumour-like nodule composed of an overgrowth of mature cells and tissues normally present in the affected part, but with disorganisation and often with one element predominating

Angiosarcoma of the Heart (right atrium)
(See Picture Below)
(A) Initial echocardiogram apical four-chamber view demonstrating pericardial tamponade and a suspected right atrial mass. **(B)** Operative photograph showing a tumour in the free wall of the right atrium. **(C)** High-power section showing a malignant spindle cell tumour with spaces filled with red blood cells, typical of angiosarcoma

There are also malignant tumours of the heart, namely:

[Picture Credit: Angiosarcoma of the Heart]

- angiosarcoma – an angiosarcoma (AS) is an uncommon malignant neoplasms characterised by rapidly proliferating, extensively infiltrating anaplastic cells derived from blood vessels and lining irregular blood-filled spaces. Specialists apply the term angiosarcoma to a wide range of malignant endothelial vascular neoplasms that affect a variety of sites. Angiosarcomas are aggressive and tend to recur locally, spread widely, and have a high rate of lymph node and systemic metastases (spread to other parts of the body). The rate of tumour-related death is high

- cardiac sarcoma - Cardiac sarcoma is a type of tumour that occurs in the heart. Cardiac sarcoma is a primary malignant (cancerous) tumour.

(Onlinecancerguide; The Free Dictionary; Medscape; Stanford Hospital and Clinics).

Signs and Symptoms of Heart Cancer

Primary heart cancer is a relatively rare form of cancer that begins as a malignant tumour within the tissue of the heart. Often referred to as a cardiac sarcoma, the abnormal cells develop in certain sections of the heart more so than others, such as the right atrium or along the outer layer of the heart known as the pericardium. And much like any form of cancer, the symptoms will vary from person to person.

Pain - One of the more common symptoms of heart cancer is pain. This pain is usually isolated to the chest, but it may also diffuse out into neighbouring regions of the body. When the tumour grows, especially along the pericardium wall, it can cause fluid to accumulate within the pericardial sac, which is a protective lining that surrounds the heart. Over time, the fluid can affect the way the heart actually pumps blood and prompt some level of chest pain

Shortness of Breath - As the overall function of the heart is impacted by the growth of cancerous cells, it can eventually take a toll on the circulation of blood, limiting the amount of oxygen passed throughout the body. With a decrease of this element in the system, respiration can become altered, triggering a shortness of breath or an unexplained sensation

of feeling winded. If this condition persists, the person may become more easily fatigued or exhausted, not only from highly physical exertion, but also day-to-day activities

Palpitations – It is also not uncommon to suffer from periodic heart palpitations while living with a cardiac sarcoma. When a tumour develops within any portion of the heart, the way in which its muscles relax and contract can become affected, eliciting a change in rhythm. This can be felt as an irregular or uneven heartbeat, as well as a rapid or pounding pulse

Swelling - Another potential symptom of heart cancer is oedema (swelling within the outer extremities of the body). This is usually an indication of some sort of obstruction within the heart, limiting either the intake or output of blood from this particular vessel. As time goes by, fluid may begin to accumulate within the feet, ankles or lower legs. For others, it may even cause some distention (or swelling) within the abdominal region

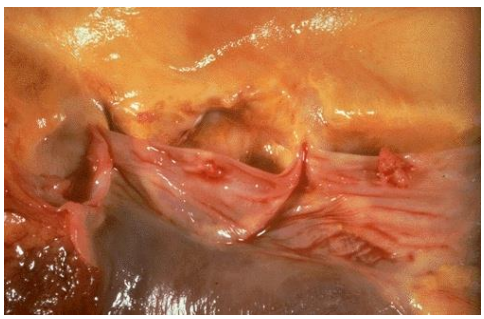
Stroke - Though not necessarily as common as other symptoms of this condition, the person may also suffer from a stroke due to a cardiac sarcoma. In this situation, the symptom is actually a result of a portion of the tumour breaking off from itself and creating a blockage within a blood vessel carrying blood to the brain. This restricts the passage of blood, oxygen and nutrients to this area of the body, causing the brain to react in this fashion

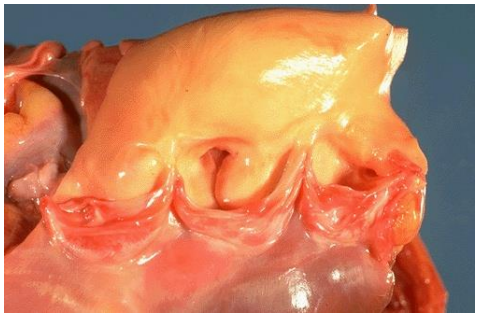
Other Symptoms - While these may be some of the more common signs of heart cancer, some people may develop other symptoms of the condition that would be considered 'non-specific' to the disease. For some, a sarcoma of the heart may elicit night sweats or a loss in weight. Others may begin to experience an elevation in body temperature, resulting in periodic fevers. Some may even go into heart failure due to the cancerous growth. How symptoms manifest depends on the individual, the location of the malignant tissue and the stage of the disease (eHow).
Although rare, most cancers found in the heart have come from elsewhere in the body. These include lymphomas that originate in the chest near the heart. Other cancers that can spread to the heart include melanomas and sarcomas.

Heart cancer may cause the following:

- Obstruction of blood flow through the heart
- Stiffening of the heart muscle (cardiac fibrosis)
- Interference with heart valves (marantic endocarditis - a spectrum of lesions ranging from microscopic aggregates of platelets to large vegetations on previously undamaged heart valves (most often aortic and mitral) in the absence of a bloodstream bacterial infection.)

(Mayo Clinic).


[Picture Credit: Marantic Endocarditis]

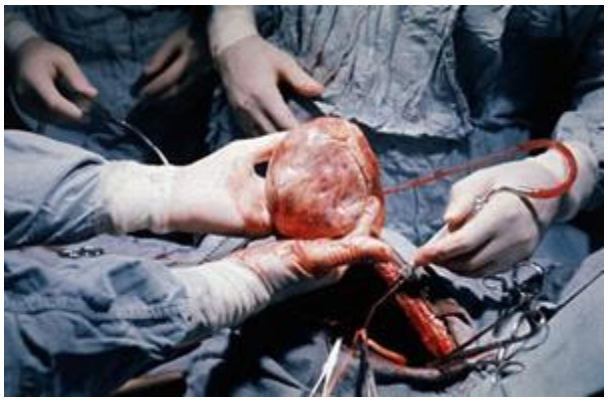

[Picture Credit: Normal Heart Valves]

Treatment of Heart Cancer

Heart cancer treatment includes various techniques such as surgery, chemotherapy, radiation therapy and palliative therapy. In order to cure this cancer, it is extremely important to perform the appropriate treatment for the cancer as soon as it is detected.

Surgery - Surgery is the most preferred treatment in the early stages of the tumour. In this process, a hole is created near the heart and the tumour and the malignant cells are completely removed from the body with the help of several techniques. After this process, some medications are prescribed for a period of time. These medications help prevent heart cancer tumour recurrence. This form of treatment has been criticised and avoided in the advanced stages because there are 30 to 40 per cent chances of recurrence of the tumour. Completely removing the malignant cells from the body through this technique is practically impossible.

In recent years, heart transplantation has sometimes been performed in selected patients with cardiac sarcoma. Orthotopic cardiac transplant has surfaced as a treatment alternative for these patients given the poor results of conventional treatment. Cardiac transplant must only be considered in highly selected patients.


Removal of a Diseased Heart.

[Picture Credit: Removal of a Diseased Heart]


Receiving a New Heart

[Picture Credit: Receiving a New Heart]

Chemotherapy - This therapy aims at removing the cancer cells with the help of drugs. In this therapy, several drugs are prescribed and a certain time span of treatment is set. These drugs travel throughout the body and destroy the tumour and the malignant cells. A study done by American Cancer Care shows the chemotherapy ensures 80 per cent removal of the tumour and the malignant cells from the body. However, these drugs have several side effects and cannot be taken for a long period of time. Some of the side-effects of this tumour include rashes over the skin, skin allergies, weight loss, hair loss and appetite loss. They

also tend to damage the immune system and so this therapy and medication of heart cancer is generally followed by nutrition therapy. In this therapy, various nutritional supplements are prescribed which may help the body to recover from the weakness caused by chemotherapy drugs.

Radiation therapy - This therapy is highly recommended and considered as the most efficient way to remove the cancer cells from the body. In this therapy, highly transmissible radioactive waves are passed through the body. These waves travel throughout the body and destroy the tumour and of the malignant cells. This therapy is highly effective and requires a short span of time. The waves that pass throughout the body tend to create weakness in the body. So this therapy is further followed by nutritional therapy.

Palliative therapy - This therapy aims at mentally preparing the patient to face their illness. In this therapy, the patient is taught on how to deal with the physical and mental issues he or she will go through throughout the treatment. Sometimes, this therapy is also combined with curative therapy. This helps the patient to improve their quality of life while facing the illness.
Heart cancer treatment options cannot guarantee the complete elimination of the tumour cells from the body. A study done by American Cancer Cure concludes that there are 20 per cent chances of reappearance of heart cancer, no matter how effective the treatment performed is. However, performing these treatments at least help to provide temporary relief from the tumour cells (Cancer8; Cancer Research UK; Mazuecos, *et al*., 2003).

The prognosis of heart cancer is poor.

Lowering the Risk for Heart Cancer

Heart cancer is a life-threatening type of tumour that occurs when the malignant cells attack the tissues of the heart. This cancer occurs rarely and people suffering from serious heart diseases are prone to this cancer. The risk for heart cancer can be lowered by keeping the heart healthy by eating healthy food stuffs and providing the body with sufficient amount of exercise. There is no certain age group for this tumour and it can occur at any age (Cancer8).

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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