Cancer Association of South Africa (CANSA)

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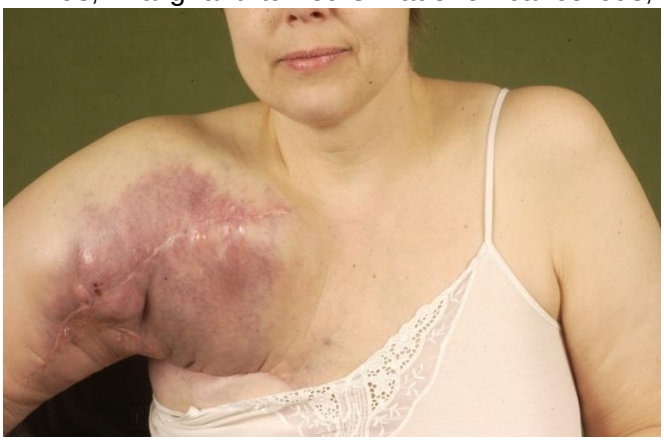
Fact Sheet on Spindle Cell Sarcoma

Introduction

A sarcoma (from the Greek σάρξ *sarx* meaning 'flesh') is a cancer that arises from transformed cells of mesenchymal origin. Thus, malignant tumours made of cancellous, cartilage, fat, muscle, vascular, or haematopoietic tissues are, by definition, considered sarcomas. This is in contrast to a malignant tumour originating from epithelial cells, which are termed carcinoma. Human sarcomas are quite rare. Common malignancies, such as breast, colon, and lung cancer, are almost always 'carcinoma'.
(Wikipedia).



[Picture Credit: Soft Tissue Sarcoma]

Cells of mesenchymal origin are are multipotent stromal cells that can differentiate into a variety of cell types, including: osteoblasts (bone cells), chondrocytes (cartilage cells), myocytes (muscle cells) and adipocytes (fat cells). Mesenchymal cells can migrate easily, in contrast to epithelial cells, which lack mobility.

Sarcomas are rare cancers that develop in the muscle, bone, nerves, cartilage, tendons, blood vessels and the fatty and fibrous tissues.

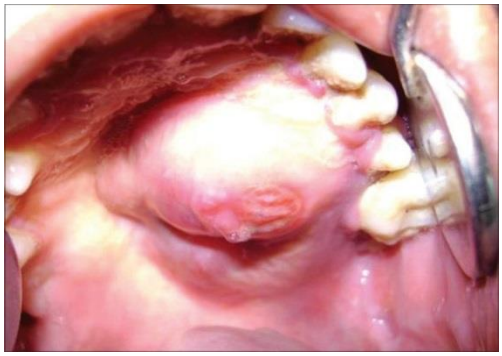
There are about 100 different types of sarcoma that fall into three main types:

- Soft tissue sarcoma
- Bone sarcoma
- Gastro-intestinal stromal tumours (GIST)

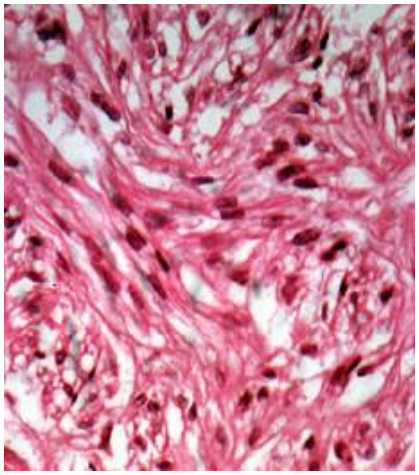
Sarcomas can affect almost any part of the body, on the inside or the outside. Sarcomas commonly affect the arms, legs and trunk. They also appear in the stomach and intestines as well as behind the abdomen (retroperitoneal sarcomas) and the female reproductive system (gynaecological sarcomas).
(Sarcoma.org.uk).

Spindle Cell Sarcoma

Spindle cell sarcoma is a type of connective tissue cancer in which the cells are spindle-shaped when examined under a microscope (see image below). The tumours generally begin in layers of connective tissue such as that under the skin, between muscles, and surrounding organs, and will generally start as a small lump with inflammation that grows.
(Wikipedia).



[Picture Credit: Spindle Cell Sarcoma]



[Picture Credit: Spindle Cell Sarcoma Histopathology]

Classification of Spindle Cell Sarcoma

Adults above the age group of 40 years are more prone to spindle cell sarcoma and it has also been traced in dogs, cats and even younger humans. Medical science has identified four various differentiations of spindle cell sarcoma arising from the connective tissue.

These are:

- Undifferentiated sarcoma of the bone: In this type of sarcoma the cells do not show proper specialisation. Since these cells do not belong to any other category of connective tissue cancerous cells they are termed as undifferentiated sarcoma cells.
- Malignant fibrous histiocytoma: This type of spindle cell sarcoma mostly affects legs and arms and is very rare. It is more common amongst middle aged adults.
- Fibrosarcoma: This type of sarcoma affects the thigh bone
- Leiomyosarcoma: Not much is known about this type of sarcoma.

(Innovateus).

Incidence of Spindle Cell Sarcoma in South Africa

The National Cancer Registry (2012) does not provide any information regarding the incidence of Spindle Cell Sarcoma.

Signs and Symptoms of Spindle Cell Sarcoma

Spindle Cell Sarcoma is usually discussed under the umbrella of Soft Tissue Sarcoma.

More than half of sarcomas begin in an arm or leg. Most people simply notice a lump that has grown over a period of time (weeks to months). Although the lump is often not painful, in some cases it will hurt. When sarcomas grow in the back of the abdomen (the retroperitoneum), the symptoms they cause more often come from other problems. Sometimes the tumours cause pain.

They may also cause blockage or bleeding of the stomach or bowels. They can grow large enough for the tumour to be felt in the abdomen. About 20% of sarcomas begin in the abdomen (stomach) area. Sarcomas can also begin on the outside of the chest or abdomen (about 10%) or in the head or neck area (around 10%).

Individuals who have any of the following problems, should see a doctor right away:

- A new lump or a lump that is growing (anywhere on your body)
- Abdominal pain that is getting worse
- Blood in your stool or vomit
- Black, tarry stools (when bleeding happens in the stomach or bowels, the blood can turn black as it is digested, and it may make the stool very black and sticky)

These symptoms are more often caused by things other than sarcoma, but they still need to be checked out by a doctor (American Cancer Society).

Diagnosis of Spindle Cell Sarcoma

There are about 50 different types of soft tissue sarcomas. Diagnosis depends on where in the body the sarcoma is situated.

Imaging tests Some tests, such as a computed tomography (CT) scan or a magnetic resonance imaging (MRI) scan, are often done to look for the cause of symptoms and to find a tumour (such as a sarcoma).

Other tests may be done after a sarcoma is diagnosed to look for cancer spread.

Plain X-ray - a regular X-ray of the area with the lump may be the first test ordered. A chest X-ray may be done after the patient has been diagnosed to see if the sarcoma has spread to the lungs.

Computed Tomography Scans - the CT scan is an x-ray procedure that produces detailed, cross-sectional images of the body. Instead of taking one picture like a conventional x-ray, a CT scanner takes many pictures as it rotates around the body. A computer then combines these pictures into an image of a slice of the body. The machine will create multiple images of the part of the body being studied.

A CT scan is often done if the doctor suspects a soft tissue sarcoma in the chest, abdomen, or the retroperitoneum (the back of the abdomen). This test is also used to see if the sarcoma has spread into the lungs, liver or other organs. A CT scanner has been described as a large donut, with a narrow table in the middle opening. The patient will need to lie still on the table while the scan is being done. CT scans take longer than regular X-rays, and the patient might feel a bit confined by the ring while the pictures are being taken

Before any pictures are taken, the patient might be asked to drink about 1 to 1½ litres of a liquid called ‘oral contrast’. This helps outline the intestine more clearly. The patient may also receive an IV (intravenous) line through which a different kind of contrast dye (IV contrast) is injected. This helps better outline structures in the body. The IV contrast dye can also cause some flushing (redness and warm feeling).

Some people are allergic and get hives or, rarely, have more serious reactions like trouble breathing and low blood pressure. Patients must inform the doctor if they have ever had a reaction to any contrast material used for X-rays.

CT scans might also be done to precisely guide a biopsy needle into a tumour inside the body — the chest or abdomen, for example. For this procedure, called a CT-guided needle biopsy, the patient remains on the CT scanning table while a radiologist advances a biopsy needle toward the location of the mass. CT scans are repeated until the doctors are sure the needle is within the mass.

Magnetic Resonance Imaging Scans - magnetic resonance imaging (MRI) scans use radio waves and strong magnets instead of X-rays to take pictures of the body. The energy from the radio waves is absorbed and then released in a pattern formed by the type of tissue and by certain diseases. A computer translates the pattern of radio waves given off by the tissues into a very detailed image of parts of the body. A contrast material might be injected, just as with CT scans, but is used less often. MRI scans are often part of the work-up of any tumour that could be a sarcoma.
MRI scans are often better than CT scans in evaluating sarcomas in the arms or legs. They provide a good picture of the extent of the tumour. They can show the health care team many things about the tumour, including location, size, and sometimes even the type of tissue it comes from (like fat or muscle). This makes MRI scans useful in planning a biopsy.

MRIs are also very helpful in examining the brain and spinal cord. MRI scans are a little more uncomfortable than CT scans. First, they take longer — often up to an hour. Also, the patient has to lie inside a long tube, which is confining and can be upsetting. MRI machines also make a thumping noise that individuals may find disturbing. Some places will provide headphones with music to block this noise out.

Ultrasound - ultrasound uses sound waves and their echoes to produce pictures of parts of the body. A small instrument called a transducer emits sound waves and picks up the echoes as they bounce off the organs. A computer converts the sound wave echoes into an image that is displayed on a computer screen. This is a very easy procedure to have. It uses no radiation, which is why it is often used to look at developing foetuses.

For most ultrasounds, the patient simply lies on a table while a technician moves the transducer over the part of your body being examined. Usually, the skin is first lubricated with gel. Ultrasound may be done before a biopsy to see if a lump is a cyst, meaning if it has fluid and is likely benign, or if it is solid and more likely a tumour. This test is often not needed if a CT or MRI was done.

Positron Emission Tomography Scan - in this test, radioactive glucose (sugar) is injected into the patient's vein to look for cancer cells. Because cancers use glucose (sugar) at a higher rate than normal tissues, the radioactivity will tend to concentrate in the cancer. A scanner can spot the radioactive deposits. A positron emission tomography (PET) scan is useful when the doctor thinks the cancer has spread but doesn't know where.

A PET scan can be used instead of several different x-rays because it scans the whole body. Often the PET scan is used with a CT scan. This helps decide if abnormalities seen on the CT scan are cancer or something else. PET is not often used for sarcoma, but it can be helpful in certain cases.

Biopsy - a biopsy is a procedure that removes a sample of tissue from a tumour to see if it is cancer. The piece of tissue is looked at under a microscope and, some other tests may be done on the sample as well. A physical examination or imaging test may suggest that a tumour is a sarcoma, but a biopsy is the only way to be certain that it is a sarcoma and not another type of cancer or a benign disease.

Several types of biopsies are used to diagnose sarcomas. Doctors experienced with these tumours will choose one, based on the size and location of the tumour. Most prefer to use a fine needle aspiration or a core needle biopsy as the first step.

Fine Needle Aspiration (FNA) Biopsy - in FNA, the doctor uses a very thin needle and a syringe to withdraw small pieces of tissue from the tumour mass. The doctor can often aim the needle while feeling the mass near the surface of the body.

If the tumour is too deep to feel, the doctor can guide the needle while viewing it on a computed tomography (CT) scan or ultrasound. The main advantage of FNA is that it can be used to biopsy tumours deep in the body without surgery. The disadvantage is that the thin needle may not remove enough tissue to make a precise diagnosis.

FNA is often useful in showing that a mass first thought to be a sarcoma (found on physical exam or imaging tests) is really another type of cancer, a benign tumour, an infection, or some other disease. But if FNA results suggest a sarcoma, another type of biopsy will usually be done to remove enough tissue to confirm that diagnosis.

After a sarcoma is diagnosed, FNA is most useful in determining whether additional tumours in other organs are metastases.

Core Needle Biopsy - core needle biopsies use a needle that is larger than the FNA needle. Sometimes this needle is called a Tru-Cut needle. It removes a cylindrical piece of tissue about 1/16 inch across and 1/2 inch long. It usually removes enough tissue to see if a sarcoma is present. Like FNA, CT scan and ultrasound can be used to guide the needle into tumours of internal organs.

Surgical Biopsy - in a surgical biopsy, the entire tumour or a piece of the tumour is removed during an operation. There are 2 types of surgical biopsies, excisional and incisional. In an excisional biopsy, the surgeon removes the entire tumour. In an incisional biopsy, only a piece of a large tumour is removed. An incisional biopsy almost always removes enough tissue to diagnose the exact type and grade of sarcoma. If the tumour is near the skin surface, this is a simple operation that can be done with local or regional anaesthesia (numbing medication given near the mass or into a nerve). But if the tumour is deep inside the body, general anaesthesia is used (the patient is asleep).

If a tumour is rather small, near the surface of the body, and not located near critical tissues (such as important nerves or large blood vessels), the doctor may choose to remove the entire mass and a margin of normal tissue in an excisional biopsy. This surgery combines the biopsy and the treatment into one operation, so it should only be done by a surgeon with experience in treating sarcomas. If the tumour is large, then an incisional biopsy is needed.

Only a surgeon experienced in sarcoma treatment should perform this procedure. Patients might want to ask about the surgeon's experience with this procedure. Proper biopsy

technique is a very important part of successfully treating soft tissue sarcomas. An improper biopsy can lead to tumour spread and problems removing the tumour later on.

An incisional biopsy in the wrong place or an excision without wide enough margins can make it harder to completely remove a sarcoma later on. To prevent these problems, these 2 types of biopsies should only be done by a surgeon experienced in treating sarcomas. It is best that an incisional biopsy be done by the same surgeon who will later remove the entire tumour (if a sarcoma is found).
(American Cancer Society)

Grading of Soft Tissue Sarcomas
If a sarcoma is present, the biopsy will be used to determine what type it is and its grade. The grade of a sarcoma is based on how the cancer cells look under the microscope. In grading a cancer, the pathologist (a doctor who specialises in diagnosing diseases by looking at the tissue under a microscope) considers how closely the tumour resembles normal tissue (differentiation), how many of the cells appear to be dividing, and how much of the tumour is made up of dying tissue.

Each factor is given a score, and the scores are added to determine the grade of the tumour.

Sarcomas that have cells that look more normal and have fewer cells dividing are generally placed in a low-grade category. Low-grade tumours tend to be slow growing, slower to spread, and often have a better outlook (prognosis) than higher-grade tumours.

Certain types of sarcoma are automatically given higher differentiation scores. This affects the overall score so much that they are never considered low grade. Examples of these include synovial sarcomas and embryonal sarcomas.

The grade is partly used to determine the stage of a sarcoma. The official staging system divides sarcomas into 3 grades (1 to 3). The grade of a sarcoma helps predict how rapidly it will grow and spread. It is useful in predicting a patient's outlook and helps determine treatment options.
(American Cancer Society).

Treatment of Spindle Cell Sarcoma
Spindle Cell Sarcoma Treatment can be done in a better way if it is detected in the first stage. If the cancer has reached to its upper stage it becomes quite tough for the physician. In the early stages surgery is the best route, but when the cancer has reached to its upper stage, only chemotherapy is the option. So, it is easier for a doctor if sarcoma has been detected at its first stage.

Before undergoing treatment, one must know what the reasons for cancer are. The prime reason for this sarcoma is often heredity. This sarcoma spreads from one generation to another through genes. Apart from heredity, one may be affected by this disease due to any external injury.

Injury often develops into this condition if the injury is not diagnosed and treated properly. The cells inside the wound develop into spindle shaped and they become cancerous. So, doctors try to find out the reason which has led to this condition for proper treatment.

If the physician has detected it in its early stages it is quite easy for the doctor to find suitable treatment procedures. Early on the tumours are fixed at one particular place. The tumour can usually be successfully removed by means of surgery at this point.

But if the stage of the rumour has increased to stage 2-3, then it becomes more difficult to remove. Chemotherapy then becomes the best form of treatment.

There are various ways in treating cancers and it depends on the origin and stage of cancer. For example, if it is near a vital organ such as the lungs or the heart, surgical removal is not the primary option. On the other hand, if it is in the limbs, wide surgical amputation is recommended to ensure complete removal of cancer cells.

The first line treatment for spindle cell sarcoma is surgical removal, cryotherapy, radiotherapy, hormone therapy and chemotherapy. The treatment of spindle cell sarcoma is selected independently depending on the location and size of the tumour. Combination therapy may also be decided upon for best results.

The most common spindle cell sarcoma treatment is surgical removal. The surgical removal treatment for spindle cell sarcoma has two types: conservative removal and wide surgical removal. Doctors recommend wide surgical removal to ensure removal of all cancer cells. To ensure that no single cancer cell is left during surgery, radiotherapy and chemotherapy is often included.

In cases where surgical removal is not possible, doctors go to the next options which include chemotherapy and radiation therapy.
(Spindle Cell Sarcoma).

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

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

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

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

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

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

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

Where Clinical Trials are Conducted

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

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

Research Team

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

Clinical Trial Protocol

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

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

National and International Regulations

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

Informed Consent

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

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

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

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

Phases of a Clinical Trial

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

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

treatment exists. Although evaluating the effectiveness of interventions is not a primary goal of these trials, doctors do look for evidence that the interventions might be useful as treatments.

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

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

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

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

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

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

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

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

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

Use of Placebos

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

Possible benefits of taking part in a clinical trial

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

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

Potential harms associated with taking part in a clinical trial

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

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

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

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

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

When a clinical trial is over

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

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

Medical Disclaimer

This Fact Sheet is intended to provide general information only and, as such, should not be considered as a substitute for advice, medically or otherwise, covering any specific condition or situation. Readers of this document should seek appropriate medical advice prior to taking or refraining from taking any action resulting from the contents of this Fact Sheet. As far as permissible by South African law, the Cancer Association of South Africa (CASNA) accepts no responsibility or liability to any person (or his/her dependants/estate/heirs) as a result of using any information contained in this Fact Sheet.

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