Cancer Association of South Africa (CANSA)

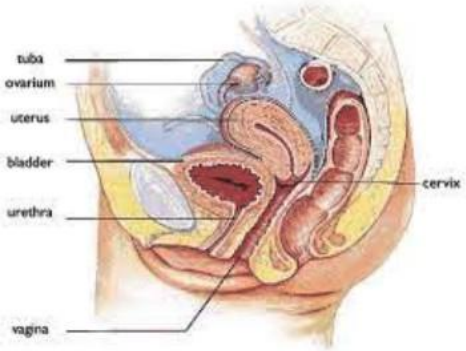
Research • Educate • Support

Fact Sheet on Cancer of the Urethra

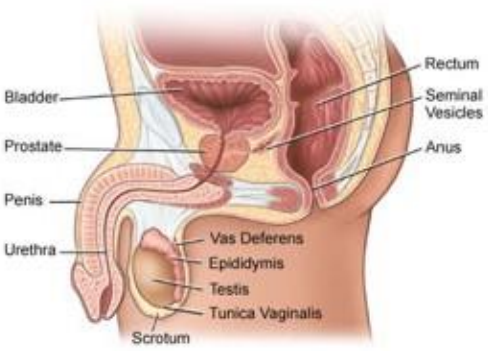
Introduction

The urethra (from Greek οὐρήθρα – *ourḗthrā*) is a tube that connects the urinary bladder to the urinary meatus for the removal of urine from the body. In males the urethra travels through the prostate and penis, and carries semen as well as urine. In females, the urethra is shorter and emerges above the vaginal opening at the external urethral orifice.

(Wikipedia).



[Picture Credit: Female Urethra]



[Picture Credit: Male Urethra]

Cancer of the Urethra

Urethral cancer is a rare type of cancer affecting the male or female urethra that comprises approximately 1 to 2 percent of all urological cancers. Urethral cancer is the only urological cancer that affects women more frequently than men. The exact cause of urethral cancer is not known. However, chronic inflammation and infection have been identified as factors that may increase the risk for developing this condition. Many men with urethral cancer have previously been treated for urethral stricture disease or sexually transmitted infections (STIs). Many women with urethral cancer have previously been treated for urethral caruncle (a deep red growth on the mucous membrane of the urinary meatus in women), urethral diverticulum or chronic urinary tract infection. In both men and women the presence of human papilloma virus (HPV) has been linked to urethral cancer. It is often associated with invasive bladder cancer. It tends to spread rapidly to surrounding tissues (the vagina and bladder for women; the penile area, prostate, and regional lymph nodes for men), and is often advanced at the time of diagnosis.

There are different types of cancer of the urethra that begin in cells that line the urethra. These cancers are named for the types of cells that become malignant (cancerous):

- Squamous cell carcinoma is the most common type of urethral cancer. It forms in cells in the part of the urethra near the bladder in women, and in the lining of the urethra in the penis in men.
- Transitional cell carcinoma forms in the area near the urethral opening in women, and in the part of the urethra that goes through the prostate gland in men.
- Adenocarcinoma forms in the glands that are around the urethra in both men and women.

(Urology Care Foundation; UCLA Health; WebMD).

Incidence of Cancer of the Urethra in South Africa

The National Cancer Registry (2012) does not provide information regarding the incidence of Cancer of the Urethra in South Africa.

Risk Factors for Cancer of the Urethra

Risk factors for cancer of the urethra include the following:

- Having a history of bladder cancer
- Having conditions that cause chronic inflammation in the urethra, including:
  - Sexually transmitted infections (STIs)
  - Frequent urinary tract infections (UTIs)
  - Human Papilloma Virus infection (HPV)
- Being 60 years of age or older
- Being a white female

(Cleveland Clinic; UCLA Health)

Signs and Symptoms of Cancer of the Urethra

Early cancer of the urethra often does not produce symptoms. As the disease progresses, symptoms include the following:

- Blood in the urine (haematuria)
- Diminished urine stream and straining to void (caused by urethral stricture)
- Frequent urination and increased night time urination (nocturia)
- Hardening of tissue in the perineum, labia, or penis
- Itching
- Incontinence
- Pain during or after sexual intercourse (dyspareunia)
- Painful urination (dysuria)
- Recurrent urinary tract infection
- Urethral discharge and swelling

Advanced cases of urethral cancer may produce swollen lymph nodes in the groin.
(UCLA Health; HealthCommunities.com).

Diagnosis and Staging of Cancer of the Urethra
After urethral cancer has been diagnosed, tests are done to find out if cancer cells have spread within the urethra or to other parts of the body.

The process used to find out if cancer has spread within the urethra or to other parts of the body is called staging. The information gathered from the staging process determines the stage of the disease. It is important to know the stage in order to plan treatment. The following procedures may be used in the staging process:

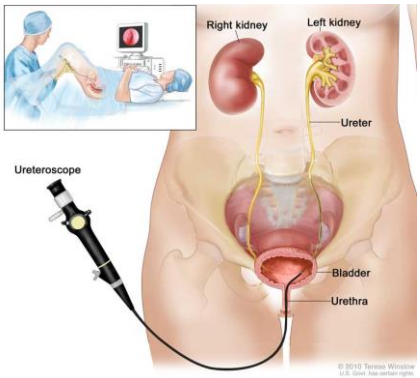
- Chest X-Ray: An X-ray of the organs and bones inside the chest. An X-ray is a type of energy beam that can go through the body and onto film, making a picture of areas inside the body
- CT Scan (CAT scan) of the pelvis and abdomen: A procedure that makes a series of detailed pictures of the pelvis and abdomen, taken from different angles. The pictures are made by a computer linked to an X-ray machine. A dye may be injected into a vein or swallowed to help the organs or tissues show up more clearly. This procedure is also called computed tomography, computerised tomography, or computerised axial tomography
- MRI (magnetic resonance imaging): A procedure that uses a magnet, radio waves, and a computer to make a series of detailed pictures of the urethra, nearby lymph nodes, and other soft tissue and bones in the pelvis. A substance called gadolinium is injected into the patient through a vein. The gadolinium collects around the cancer cells so they show up brighter in the picture. This procedure is also called nuclear magnetic resonance imaging (NMRI)
- Blood chemistry studies: A procedure in which a blood sample is checked to measure the amounts of certain substances released into the blood by organs and tissues in the body. An unusual (higher or lower than normal) amount of a substance can be a sign of disease in the organ or tissue that produces it
- Complete Blood Count (CBC): A procedure in which a sample of blood is drawn and checked for the following:

    - The number of red blood cells, white blood cells, and platelets
    - The amount of haemoglobin (the protein that carries oxygen) in the red blood cells
    - The portion of the blood sample made up of red blood cells

- Physical examination and health history: An examination of the body to check general signs of health, including checking for signs of disease, such as lumps or anything else that seems unusual. A history of the patient's health habits and past illnesses and treatments will also be taken
- Pelvic examination: An examination of the vagina, cervix, uterus, fallopian tubes, ovaries, and rectum in the female. The doctor inserts one or two lubricated, gloved fingers of one hand into the vagina and places the other hand over the lower abdomen to feel the size, shape, and position of the uterus and ovaries. A speculum is also inserted into the vagina and the doctor looks at the vagina and cervix for signs of disease
- Digital rectal exam: An examination of the rectum in a male. The doctor inserts a lubricated, gloved finger into the lower part of the rectum to feel for lumps or anything else that seems unusual
- Urine cytology: Examination of urine under a microscope to check for abnormal cells
- Urinalysis: A test to check the colour of urine and its contents, such as sugar, protein, blood, and white blood cells. If white blood cells (a sign of infection) are found, a urine culture is usually done to find out what type of infection it is
- Ureteroscopy: A procedure to look inside the ureter and renal pelvis to check for abnormal areas. A ureteroscope is a thin, tube-like instrument with a light and a lens

for viewing. The ureteroscope is inserted through the urethra into the bladder, ureter, and renal pelvis. A tool may be inserted through the ureteroscope to take tissue samples to be checked under a microscope for signs of disease

[Picture Credit: Ureteroscope]



- Biopsy: The removal of cell or tissue samples from the urethra, bladder, and, sometimes, the prostate gland. The samples are viewed under a microscope by a pathologist to check for signs of cancer.

Three ways that cancer spreads in the body are:

- Through tissue. Cancer invades the surrounding normal tissue.
- Through the lymph system. Cancer invades the lymph system and travels through the lymph vessels to other places in the body.
- Through the blood. Cancer invades the veins and capillaries and travels through the blood to other places in the body.

When cancer cells break away from the primary (original) tumour and travel through the lymph or blood to other places in the body, another (secondary) tumour may form. This process is called metastasis. The secondary (metastatic) tumour is the same type of cancer as the primary tumour. For example, if breast cancer spreads to the bones, the cancer cells in the bones are actually breast cancer cells. The disease is metastatic breast cancer, not bone cancer.

Urethral cancer is staged and treated based on the part of the urethra that is affected and how deeply the tumour has spread into tissue around the urethra. Urethral cancer can be described as anterior or posterior urethral cancer.

Anterior urethral cancer - in anterior urethral cancer, the tumours are not deep and they affect the part of the urethra that is closest to the outside of the body.

Posterior urethral cancer - in posterior urethral cancer, the tumours are deep and affect the part of the urethra closest to the bladder. In women, the entire urethra may be affected. In men, the prostate gland may be affected.

<u>Stage 0 (Carcinoma in Situ)</u>
In stage 0, abnormal cells are found in the inside lining of the urethra. These abnormal cells may become cancerous and spread into nearby normal tissue. Stage 0 is also called carcinoma in situ.

<u>Stage A</u>
In stage A, cancer has formed and spread into the layer of tissue beneath the lining of the urethra.

<u>Stage B</u>
In stage B, cancer is found in the muscle around the urethra. In men, the penile tissue surrounding the urethra may be affected.

<u>Stage C</u>
In stage C, cancer has spread beyond the tissue surrounding the urethra, and:

- in women, may be found in the vagina, vaginal lips, or nearby muscle
- in men, may be found in the penis or in nearby muscle

Stage D

Stage D is divided into stage D1 and stage D2, based on where the cancer has spread:

- In stage D1, cancer has spread to nearby lymph nodes in the pelvis and groin
- In stage D2, cancer has spread to distant lymph nodes or to other organs in the body, such as the lungs, liver, and bone

Recurrent Urethral Cancer - recurrent urethral cancer is cancer that has recurred (come back) after it has been treated. The cancer may come back in the urethra or in other parts of the body.

TNM staging system

In men and women, urethral cancer (UC) is classified according to the 7th edition of the TNM classification. It should be noted that there is a separate TNM staging system for prostatic UC. Of note, for cancers occurring in urethral diverticulum stage T2 is not applicable as urethral diverticula are lacking periurethral muscle.

TNM classification (7th edition) for UC (8). Primary tumour stage is separated into UC and UC of the prostate:

T - Primary tumour (men and women)

Tx Primary tumour cannot be assessed
Tis Carcinoma in situ
T0 No evidence of primary tumour
Ta Non-invasive papillary carcinoma
T1 Tumour invades subepithelial connective tissue
T2 Tumour invades any of the following structures: corpus spongiosum, prostate, peri-urethral muscle
T3 Tumour invades any of the following structures: corpus cavernosum, invasion beyond prostatic capsule, anterior vaginal wall, bladder neck
T4 Tumour invades other adjacent organs

Primary tumour in prostatic urethra

Tx Primary tumour cannot be assessed
Tis pu Carcinoma in situ in the prostatic urethra
Tis pd Carcinoma in situ in the prostatic ducts
T0 No evidence of primary tumour
T1 Tumour invades subepithelial connective tissue (only in case of concomitant prostatic urethral involvement)
T2 Tumour invades any of the following structures: corpus spongiosum, prostatic stroma, periurethral muscle
T3 Tumour invades any of the following structures: corpus cavernosum, beyond prostatic capsule, bladder neck
T4 Tumour invades other adjacent organs

N - Regional lymph nodes

Nx Regional lymph nodes cannot be assessed
N0 No regional lymph node metastases

N1 Metastasis in a single lymph node < 2 cm in greatest dimension
N2 Metastasis in a single lymph node > 2 cm in greatest dimension or in multiple nodes

M - Distant metastasis

Mx Distant metastasis cannot be assessed
M0 No distant metastasis
M1 Distant metastasis
(MedicineNet.com; WebMD; Gakis, *et al*., 2014).

Treatment of Cancer of the Urethra
The following treatment is used in cases of cancer of the urethra:

Surgery - In the female, most tumours present with bleeding or distal urethral mass. Distal urethral or anterior lesions usually present early and are diagnosed while at low stage. These tumours have been successfully managed with local excision, transurethral resection, partial urethrectomy, and fulguration or ablation with either neodymium: YAG or CO_2 laser techniques. In rare instances, higher stage local lesions may be managed with total urethrectomy and preservation of the bladder with interposition of a catheterisable segment or with the Mitrofanoff procedure (catheterisable urinary stoma).

More proximal lesions present later and at higher stage than distal lesions. Progressive obstructive symptoms are the hallmark of proximal or 'posterior' urethral lesions. For superficial tumours, transurethral resection or laser surgery may be appropriate. Advanced or extensive lesions, and those which involve the bladder or vagina, may necessitate cystectomy or anterior exenteration with urinary diversion. Local recurrence in such high-stage disease occurs frequently.

In advanced disease, metastases to the lymph nodes are present in 50% of cases. Inguinal node dissection should be performed in the presence of palpably enlarged nodes, and pelvic node dissection should be performed when proximal involvement of the urethra is identified. There does not appear to be any therapeutic advantage to prophylactic node dissection when the inguinal nodes are not enlarged.

In the male patient low-grade, low-stage tumours of the urethra may lend themselves to transurethral resection or laser fulguration, but such lesions are rare. Excisional biopsy may be feasible, and biopsy prior to laser fulguration is essential to assess histopathology and tumour depth.

Selected lesions of the distal urethra may lend themselves to partial penectomy (removal of the penis through surgery). Tumours must not involve the corpus spongiosum or the corpora cavernosa, and must be amenable to a 2-cm margin. More advanced or more proximal lesions may require a total penectomy with creation of a perineal urethrostomy (artificial opening for urine to pass through). Proximal cancers may necessitate an anterior exenteration with radical cystoprostatourethrectomy and urinary diversion.

Inguinal and pelvic lymphadenopathy portends metastatic disease. Careful serial palpation of the groins as well as interval pelvic CT evaluations are essential in the follow-up of definitive treatment of a urethral primary. Inguinal node dissection should be performed in the presence of clinically positive groin nodes. This has been curative in many cases. In

several small series, 5-year survival following inguinal node dissection ranged from 12% to 66%. Pelvic node dissection has also proven curative in an occasional case and is worthwhile, although the prognosis in pelvic nodal disease is much worse than with inguinal node involvement. In the absence of inguinal adenopathy, inguinal lymphadenectomy is probably not warranted.

Radiation Therapy - Radiation therapy, administered as both external beam radiation and brachytherapy, has been used for definitive treatment of both localised and advanced tumours. It has also been used to downsize tumours before definitive surgical intervention. Results have been mixed, with 5-year survivals averaging approximately 35% in advanced disease. Side effects and complications, including oedema, fistulae, and damage to the bowel, are commonplace.

Chemotherapy and Combined Therapy - The rarity of these tumours has precluded much meaningful clinical research in chemotherapeutic treatment, or in chemotherapy combined with radiation or surgery. Combination chemotherapy in conjunction with radiation and surgery has produced promising outcomes in squamous carcinomas of the head and neck, anus, and penis, and may be expected to demonstrate similar benefit in squamous cancers of the urethra. However, multinational, multi-institutional trials are required to provide clinical data to assess the efficacy of any such treatment regimens.
(NCBI).

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 minimise 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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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 situation. Users should seek appropriate advice before taking or refraining from taking any action in reliance on any information contained in this Fact Sheet. So far as permissible by law, the Cancer Association of South Africa (CANSA) does not accept any liability to any person (or his/her dependants/estate/heirs) relating to the use of any information contained in this Fact Sheet.

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