

Cancer Association of South Africa (CANSA)



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Fact Sheet on Pancoast Tumour

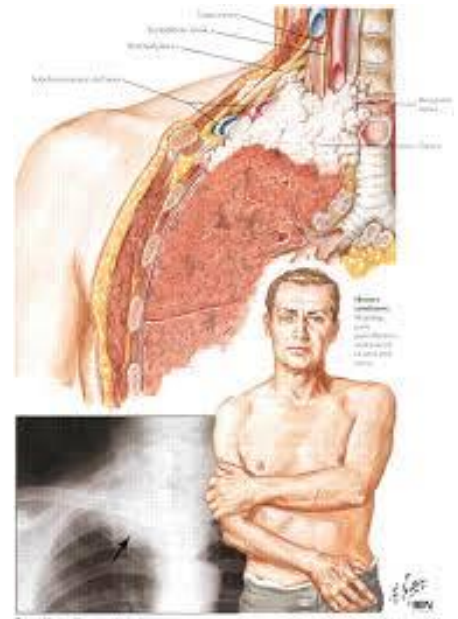
Introduction

The thoracic cage (rib cage) is an arrangement of bones in the chest (thorax) of all vertebrates. It is formed by the vertebral spine, ribs and sternum and encloses the heart and lungs. The thoracic cage, is a bony and cartilaginous structure which surrounds the thoracic cavity and supports the shoulder girdle, forming a core portion of the human skeleton. A typical human rib cage consists of 24 ribs, the sternum, costal cartilages, and the 12 thoracic vertebrae. Together with the skin and associated fascia and muscles, the rib cage makes up the thoracic wall and provides attachments for the muscles of the neck, thorax (chest), upper abdomen, and back. It also contains the pulmonary sulcus which houses the upper portions of the lungs.

(Wikipedia).

The pulmonary groove (sulcus) is a deep vertical recess formed on either side of the thoracic cage by the posterior curvature of the ribs – it contains the uppermost posterior portions of the lungs. Synonyms include: sulcus pulmonalis; paravertebral gutter; pulmonary sulcus.

(The Free Dictionary).



Pancoast Tumour

Pancoast tumours are lung cancers that form at the extreme apex (very top) of either the right or left lung in the superior sulcus (a shallow furrow on the surface of the lung).

Pancoast tells one where the cancer is, rather than what type it is. These cancers were named after an American doctor called Professor Henry Pancoast in 1932. Pancoast tumours grow right at the top of the lung (the apex). This position makes them rare because most lung cancers develop lower down in the lungs. Fewer than 5 in every 100 cases of lung cancer (5%) are Pancoast tumours.

Because of their location in the apex of the lung, they invade adjoining tissue. They form an abnormal patch of tissue over the lung apex and principally involve the chest wall structures rather than the underlying lung tissue. They invade the following structures:

- Lymphatics (small, thin vessels that carry lymph fluid through the body)
- Lower roots of the brachial plexus (a complex network of nerves that is formed chiefly by the lower 4 cervical [neck] nerves and the first thoracic [chest] nerve)
- Intercostal nerves (nerves that lie between a pair of adjacent ribs)
- Stellate ganglion (a mass of nerve tissue containing nerve cells that form an enlargement on a nerve or on 2 or more nerves at their point of junction or separation)
- Sympathetic chain (either of the pair of ganglionated lengthwise cords of the sympathetic nervous system that are situated on each side of the spinal column)
- Adjacent ribs
- Vertebrae

Most Pancoast tumours are non-small-cell cancers and most commonly squamous cell cancers. Between 35 and 40 out of every 100 lung cancers diagnosed (35 to 40%) are squamous cell cancers. These cancers develop from the cells that line the airways.

Pancoast tumours can be difficult to diagnose. This is because:

- They often do not show up easily on X-ray – one may need an MRI scan to help diagnose the cancer
- The symptoms are unusual and this may lead a doctor to suspect other conditions before lung cancer

(eMedicineHealth; Cancer Research UK; WebMD).

Incidence of Pancoast Tumour in South Africa

The South African National Cancer Registry (2013) does not provide any information regarding the incidence of Pancoast Tumour.

According to the National Cancer Registry (2013) the following number of lung cancer cases was histologically diagnosed in South Africa during 2013:

Group - Males 2013	Actual No of Cases	Estimated Lifetime Risk	Percentage of All Cancers
All males	1 766	1:76	4,91%
Asian males	80	1:59	9,65%
Black males	691	1:131	6,42%
Coloured males	361	1:35	8,65%
White males	636	1:47	3,15%

Group - Females 2013	Actual No of Cases	Estimated Lifetime Risk	Percentage of All Cancers
All females	923	1:205	2,52%
Asian females	33	1:179	3,15%
Black females	241	1:547	1,54%
Coloured females	207	1:78	5,09%
White females	443	1:78	2,79%

The frequency of histologically diagnosed cases of lung cancer in South Africa for 2013 was as follows (National Cancer Registry, 2013):

Group - Males 2013	0 – 19 Years	20 – 29 Years	30 – 39 Years	40 – 49 Years	50 – 59 Years	60 – 69 Years	70 – 79 Years	80+ Years
All males	3	1	26	207	522	592	322	72
Asian males	0	0	1	9	17	30	18	2
Black males	1	1	8	95	241	208	73	20
Coloured males	0	0	5	45	107	118	64	3
White males	2	0	11	51	136	210	153	45

Group - Females 2013	0 – 19 Years	20 – 29 Years	30 – 39 Years	40 – 49 Years	50 – 59 Years	60 – 69 Years	70 – 79 Years	80+ Years
All females	1	1	27	80	238	295	224	52
Asian females	0	0	0	1	14	10	6	0
Black females	1	0	13	26	58	72	43	13
Coloured females	0	0	5	16	58	70	38	9
White females	0	1	7	27	94	136	125	28

N.B. In the event that the totals in any of the above tables do not tally, this may be the result of uncertainties as to the age, race or sex of the individual. The totals for 'all males' and 'all females', however, always reflect the correct totals.

Signs and Symptoms of Pancoast Tumour

Because the cancer is at the top of the lungs, it may put pressure on or damage a group of nerves (the brachial plexus) that runs from the upper chest into one's neck, face and arms. This can cause several very specific symptoms:

- Severe pain in the shoulder or the shoulder blade (scapula)
- Pain in the arm and weakness of the hand on the affected side
- Horner's syndrome.

[Picture Credit: Horner's Syndrome]

Horner's syndrome is the medical name for a group of symptoms. One gets flushing on one side of the face and that side does not sweat. The eye on the same side has a smaller (constricted) pupil with a drooping or weak eyelid.

(Cancer Research UK).



Risk Factors for Pancoast Tumour

The risk factors for almost all lung cancers are similar.

These include:

- Use of tobacco products
- Secondary smoke exposure
- Asbestos exposure
- Exposure to industrial elements (e.g. gold, nickel).

(WebMD).

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Diagnosis of Pancoast Tumour

Imaging and biopsy are the cornerstones of evaluation of Pancoast Tumour. The apex of the lung can be difficult to investigate because it is bounded laterally by the first rib, posteriorly by the first rib and the vertebral bodies, and anteriorly by the costal cartilage of the first rib and the manubrium. Plain radiographs of the chest frequently show no change or an asymmetry or thickening of the apical cap. Apical lordotic films may be more revealing. Computed tomography (CT) and magnetic resonance imaging (MRI) have become standard. In very rare cases, sputum cytology has been helpful. Initially, most Pancoast tumours are diagnosed histologically on the basis of transthoracic needle biopsy results. Diagnosis via bronchoscopy is less helpful because most of these tumours are peripherally located. The flexible scope is more useful than the rigid scope in obtaining bronchoscopic aspirates and brush biopsy specimens.

Liver, bone, and brain scans are performed to look for metastatic disease. Although more than 90% of patients can be correctly diagnosed on the basis of clinical and radiologic findings alone, open biopsy for pathologic validation may be performed through a supraclavicular incision. Results from a needle biopsy through the supraclavicular or posterior triangle are also successful in confirming the diagnosis and in delineating the cell type before treatment. Even though clinical diagnosis is relatively simple, performing a tissue biopsy is still necessary.

Laboratory Studies

The blood workup for patients with Pancoast tumours is not specific, and results are not diagnostic.

Lung cancers produce various substances. Elevated levels of oncofoetal carcinoembryonic antigen and beta-2 microglobulins are associated with many lung cancers. Unfortunately, these findings are not diagnostic, because levels of these chemicals are also elevated by other nonspecific causes, such as smoking and bronchitis.

Tumour markers (e.g., bombesin, neuron-specific enolase, and other peptides) are common with small cell cancers and are related to the stage of the disease. They may aid in distinguishing differentiated forms of lung cancer from undifferentiated forms.

Various tumour oncogenes, including *K-ras*, *c-myc*, *TP53*, and *HER-2/neu*, have also been identified in patients with lung cancers. Although the presence of these oncogenes has some prognostic value, they are not important for staging of the cancer.

Routine blood work in all patients with a lung cancer includes a complete blood count (CBC) count, blood urea nitrogen (BUN) and creatinine levels, a white blood cell (WBC) count, and urinalysis. Coagulation parameters, such as prothrombin time (PT), activated partial thromboplastin time (aPTT), and platelet count, are appropriate. Unless metastatic disease is evident, liver function tests are not regularly performed. Any patient deemed a surgical candidate has blood drawn for a cross-match.

Urinalysis is performed in all patients before surgery, and a catheter specimen is obtained in women if the initial urinalysis result suggests contamination.

Imaging Tests

CT and MRI of the neck, chest, and upper abdomen have largely replaced older radiographic studies in the workup of Pancoast Tumour.

CT is less expensive than MRI and much more available. It can help assess bone destruction and is useful in general imaging of the lung for the evaluation of mediastinal adenopathy, other pulmonary nodules, and liver involvement. CT scanning helps identify invasion of the brachial plexus, chest wall, and mediastinum, as well as reveal involvement of the vena cava, trachea, and oesophagus. Contrast CT scanning is useful for assessing subclavian vessel involvement.

MRI is useful for evaluating resectability. It may be more accurate in evaluating chest wall invasion, examining vascular structures, and assessing the brachial plexus for invasion. It is more accurate than a CT scan for assessing invasion of cervical structures and vertebral bodies.

MRI has no advantage over CT in the evaluation of the mediastinum. In fact, CT is much better than MRI for assessing the mediastinum for lymph nodes. Rib or transverse process involvement is not a sign of inoperability; however, involvement of the vertebral body makes achieving an adequate margin of resection very difficult and reduces the odds for survival.

Additional staging studies should be considered. Mediastinoscopy should be performed to evaluate mediastinal nodes. The presence of N2 mediastinal lymphadenopathy has a significant adverse effect on survival. CT or MRI of the head to exclude occult metastasis should be performed if treatment with curative intent is planned. CT of the chest can be extended to include the liver and adrenal glands.

Now that positron-emission tomography (PET) scanning has been approved by the US Food and Drug Administration for the staging of non-small cell lung cancer in general, it is increasingly being used in the setting of Pancoast syndrome.

Chest radiographs may reveal a small homogenous apical cap or pleural thickening; they may show a thin plaque at the lung apex in the area of the superior sulcus or may reveal a large mass, depending on the stage of the tumour when it is first diagnosed. Suggestive films should prompt the astute diagnostician to order apical lordotic views for better visualisation of the area.

Bone destruction of the posterior 1-3 ribs may sometimes be apparent. Rib invasion or vertebral body infiltration may be evident on a plain chest radiograph. Mediastinal enlargement may be apparent.

Brochoscopy and Biopsy

Bronchoscopy helps evaluate the tracheal and bronchial lumens; however, because most Pancoast tumours are peripheral, the diagnostic yield is low. Whereas sputum cytology results are positive in fewer than 15% of patients, fiberoptic bronchoscopy findings are more often positive - but only in 20-30% of patients, because of the peripheral location of the tumour. Bronchoscopy, however, can be useful in excluding otherwise unsuspected concurrent endobronchial lesions.

Tissue diagnosis is obtained on the basis of results from percutaneous needle biopsy, either under fluoroscopy or under CT guidance. Staging is based on scalene node biopsy results from palpable nodes or mediastinoscopy findings. If a patient presents with supraclavicular

lymph node enlargement, then a fine-needle aspiration (FNA) biopsy of enlarged supraclavicular lymph nodes or an ipsilateral supraclavicular fullness procedure is a fast, safe, and inexpensive means of confirming the diagnosis.

Transthoracic needle biopsy by CT guidance has a high yield, up to 95% in some series. Some tumours may be evaluated only by thoracotomy, either open or video assisted.

Other Tests

Rarely, arterial or venous involvement of the subclavian artery or vein occurs; thus, arteriography or phlebography may be helpful. This is usually accomplished in a retrograde fashion, although it can be approached from the opposite extremity or from the leg.

Baseline electrocardiography (ECG) is performed on all patients for comparison to postoperative ECG tracings (if one is performed).
(Medscape).

Staging of Pancoast Tumour

The stage of a cancer tells one how big it is and how far it has spread. It is important because it helps the doctor decide which treatment to administer. The tests and scans give some information about the stage. Sometimes it is not possible to be certain about the stage of a cancer until after surgery.

There are different ways of staging lung cancer. There is a number staging system and a system called the TNM system.

The number staging system

This divides lung cancers into 4 main groups

Stage 1 – the cancer is small and only in one area of the lung (localised)

Stage 2 and 3 – the cancer is larger and may have grown into the surrounding tissues and there may be cancer cells in the lymph nodes (locally advanced)

Stage 4 – the cancer has spread to another part of the body (secondary or metastatic cancer)

Doctors break down each of these stages of lung cancer into sub groups, such as stage 3a, 3b and so on.

TNM staging system

TNM stands for Tumour, Node, Metastases. This staging system describes

- The size and position of the tumour (**T**)
- Whether cancer cells have spread into the lymph nodes (**N**)
- Whether the tumour has spread anywhere else in the body – secondary cancer or metastases (**M**)

The doctor gives each factor a number. So, a very small cancer which hasn't spread is T1 N0 M0. A cancer that is larger and has spread into the lymph nodes and to another part of the body is T3, N1, M1.
(Cancer Research UK).

Treatment of Pancoast Tumour

Originally, Pancoast tumour was fatal due to involvement of vital structures at the thoracic inlet. This has improved with multimodality treatment, including induction chemoradiotherapy (usually cisplatin-based) followed by resection. Resection may involve a wedge resection or a lobectomy (surgical removal of a lobe of the lung). Traditionally, the involved brachial plexus has also been resected, leading to paralysis and neuropathic pain, but this may be unnecessary.

Involvement of vertebrae, cervical plexus and lymph nodes are all associated with poorer outcomes. Historically, five-year survival was 30-40% with complete resection and no lymph node involvement and <10% for all other groups. Two-thirds of patients experience a recurrence. However, data regarding survival rates with induction chemoradiation and resection are much better and five-year survival rates of approximately 50-70% have been reported. Mediastinal lymph node involvement is associated with a particularly poor prognosis.
(Patient.info).

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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