Cancer Association of South Africa (CANSA)

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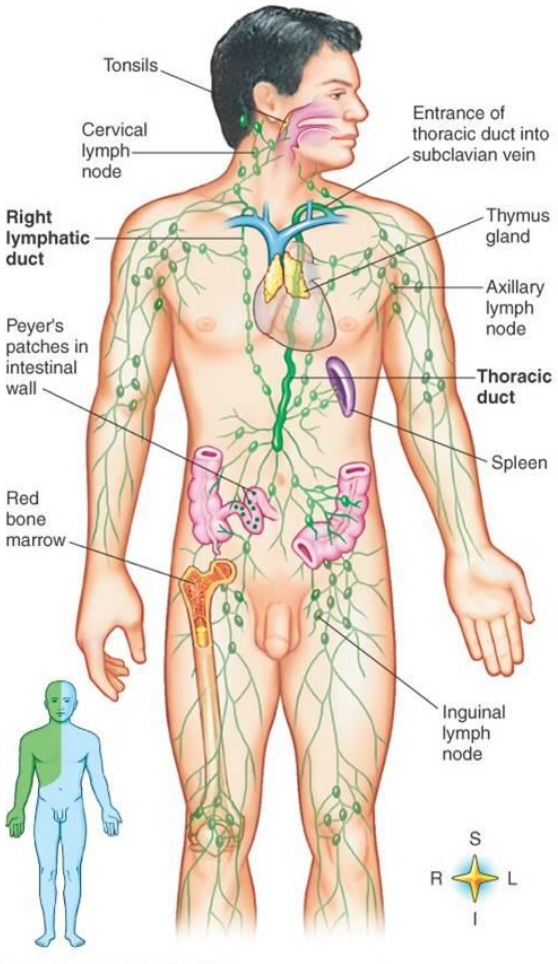
Fact Sheet
on
Thymoma

Introduction

The lymph system is made up of thin tubes that branch out to all parts of the body. The lymph system carries lymph, a colourless fluid containing a type of white blood cell called lymphocytes. Lymphocytes fight germs in the body. B-lymphocytes, or B cells, make antibodies to fight bacteria, and T-lymphocytes, or T cells, destroy viruses and foreign cells and trigger the B cells to make antibodies. The thymus is involved in the development of T-lymphocytes.



[Picture Credit: Lymphatic System]

As part of the lymph system, groups of tiny, bean-shaped organs called lymph nodes are located throughout the body at different sites. Lymph nodes are found in clusters in the abdomen, groin, pelvis, underarms, and neck. In addition to the thymus, other parts of the lymph system include the spleen, which makes lymphocytes and filters blood, and the tonsils, located in the throat.

Cancer begins when normal cells change and grow uncontrollably, forming a mass called a tumour. A tumour can be cancerous or benign. A cancerous tumour is malignant, meaning it can spread to other parts of the body. A benign tumour means the tumour will not spread. (Cancer.Net).

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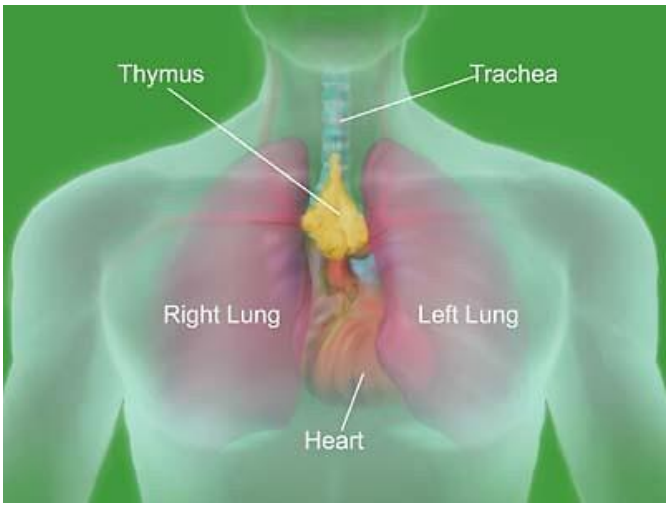
The Thymus Gland

The thymus gland will not function throughout an individual's full lifetime, but it has a big responsibility when it is active - helping the body protect itself against autoimmunity, which occurs when the immune system turns against itself. Therefore, the thymus plays a vital role in the lymphatic system (the body's defense network a*nd* endocrine system.



[Picture Credit: Thymus Gland]

Before birth and throughout childhood, the thymus is instrumental in the production and maturation of T-lymphocytes or T cells, a specific type of white blood cell that protects the body from certain threats, including viruses and infections. The thymus produces and secretes thymosin, a hormone necessary for T cell development and production.

The thymus is special in that, unlike most organs, it is at its largest in children. Once one reaches puberty, the thymus starts to slowly shrink and become replaced by fat. By age 75, the thymus is little more than fatty tissue. Fortunately, the thymus produces all of one's T cells by the time one reaches puberty.

Anatomy of the Thymus - the thymus is located in the upper anterior (front) part of the chest directly behind the sternum and between the lungs. The pinkish-gray organ has two thymic lobes. The two halves, called *lobes*. It has an irregular shape and a surface that is made up of many small bumps called *lobules*. The thymus has 3 main layers:

- The **medulla** is the innermost part of the thymus.
- The **cortex** is the layer surrounding the medulla.
- The **capsule** is the thin covering over the outside of the thymus.

The thymus reaches its maximum weight (about 28g) during puberty.

Thymosin: The Hormone of the Thymus - thymosin stimulates the development of T cells. Throughout childhood years, white blood cells called lymphocytes pass through the thymus, where they are transformed into T cells.

Once T cells have fully matured in the thymus, they migrate to the lymph nodes (groups of immune system cells) throughout the body, where they aid the immune system in fighting disease. However, some lymphocytes, regardless if they reside in the lymph nodes or thymus, can develop into cancers (known as Hodgkin disease and non-Hodgkin lymphomas).

Though the thymus gland is only active until puberty, its double-duty function as an endocrine and lymphatic gland plays a significant role in long-term health.

(EdocrineWeb; American Cancer Society).

Thymoma (Thymus Cancer)
Thymoma is cancer that develops in the thymus gland. It is the uncontrollable growth of cells that eventually forms a tumour.

Causes of Thymoma
The exact cause of thymomas is not known. Thymomas are slightly more common in men than in women and are most frequently seen in persons between the ages of 40 and 60. There are no known risk factors that predispose a person to developing thymoma.
(Medicine.Net).

The Incidence of Thymoma in South Africa
The incidence of thymoma in South Africa is not known as the National Cancer Registry (2013) does not make mention of thymoma. It is known as one of the rare cancers.

Signs and Symptoms of Thymoma
Up to 50% of thymomas are asymptomatic, meaning they do not produce any symptoms or signs and are diagnosed when an imaging study is performed for another reason. In other cases, the tumour may cause symptoms related to the size of the tumour and the pressure it exerts on adjacent organs:

- Chest pain
- shortness of breath
- cough
- Fever
- Night Sweats
- Weight loss

Some cases thymoma may spread to the lining of the lungs or heart or even to tissues outside the chest. Less than 7% of cases are accompanied by spread outside the chest cavity. Thymic carcinomas are more aggressive tumours than thymomas and are more likely to spread and to cause symptoms.
(Medicine.Net).

Thymic Carcinoma
Thymic carcinoma is a much rarer condition than thymoma. It tends to grow and develop more quickly and is more likely to spread to other parts of the body. Thymic carcinomas are found in all age groups but do remember, they are very rare. Most people do have symptoms. These include a cough and chest pain. It is much rarer to also have an autoimmune condition such as myasthenia gravis with thymic carcinoma than it is with thymoma.

Most people have treatment with surgery and either radiotherapy or chemotherapy, or both. The most common type of treatment is surgery followed by radiotherapy. The surgeon will take out as much of the tumour as possible. They then use radiotherapy to try and kill off any cancer cells left behind.

Unfortunately, thymic carcinoma is harder to cure than thymoma. This is because it often spreads quite early on. The cancer can spread to the lungs and lymph nodes in the chest. In some cases, it may also spread to the bones or to the liver. It is difficult to find reliable statistics for the outlook of rare conditions. But around a third of the people diagnosed with thymic carcinoma are likely to live for at least 5 years.
(Cancer Research UK).

Diagnosis of Thymoma
A physical examination of the patient will be done to see if there are any unusual findings such as lumps. Other tests used to diagnose thymus cancer include:

- chest X-ray
- imaging tests such as positron emission tomography (PET) scan, computed tomography (CT) scan, and magnetic resonance imaging (MRI)
- biopsy with microscopic examination of thymus cells

(Healthline).

Classification of Thymoma
Most doctors classify thymomas by how they look under a microscope and by tests done on the tissue samples. This is called the *histologic type*. The system used for this classification, which was developed by the World Health Organization (WHO), assigns letters to the different types of thymomas.

Type A:
The cells in these tumours are spindle-shaped or oval epithelial cells that appear to be fairly normal looking. This is the rarest type of thymoma, but it seems to have the best prognosis (outlook).

Type AB:
This type, also known as a *mixed thymoma*, looks like type A except that there are also areas of lymphocytes mixed in the tumour.

Type B1:
This type looks a lot like the normal structure of the thymus. It has a lot of lymphocytes along with normal-appearing thymus cells.

Type B2:
This type also has a lot of lymphocytes, but the thymus epithelial cells are larger with abnormal nuclei (the DNA-containing part of the cell).

Type B3:
This type has few lymphocytes and mostly consists of thymus epithelial cells that look pretty close to normal.

Type C:
This is the most dangerous form and is also known as *thymic carcinoma*. It contains cells that have a very abnormal appearance under the microscope. The cells may no longer even look like thymus cells. These tumours have often grown into (invaded) nearby tissues and/or metastasised (spread to distant tissues and organs) at the time they are found. This type of thymoma has the worst prognosis (outlook).

Type AB and type B2 are the most common types of thymoma, and type A is the least common. As you go from A to C, the outlook for survival tends to get worse, with type A having the best outlook, and type C having the worst. Still, for most types of thymoma, the stage (extent of growth and spread) is a better predictor of a person's outcome.
(American Cancer Society).

Staging of Thymoma
The Masaoka-Koga Staging System is mostly used:

Stage I:
Grossly and microscopically completely encapsulated tumor

Stage IIa:
Microscopic transcapsular invasion

Stage IIb:
Macroscopic invasion into thymic or surrounding fatty tissue, or grossly adherent to but not breaking through mediastinal pleura or pericardium

Stage III:
Macroscopic invasion into neighboring organ (i.e. pericardium, great vessel or lung)

Stage IVa:
Pleural or pericardial metastases

Stage IVb:
Lymphogenous or hematogenous metastasis

General criticisms that have been raised about the Masoaka and Masaoka-Koga staging systems are that there is little, if any, survival difference between stage I and II, and that stage III involves a wide spectrum ranging from transpleural adhesions without invasion to extensive macro and microscopic involvement of the aorta, pulmonary arteries and heart.
(ccehub).

Treatment of Thymoma
Treatment of thymoma is as follows:

Surgery - to remove the tumour is the most common treatment for malignant thymoma.

Chemotherapy - A few reports in the literature suggest that thymomas are chemosensitive tumours. Potential candidates for chemotherapy include approximately one third of the patients with an invasive thymoma that later metastasises and all patients with stage IV disease.

Radiation therapy - also may be used alone or in addition to surgery, especially in patients with stage 2 Thymoma.

Hormone therapy - and chemotherapy may be given either on or off a lung cancer clinical trial.

Hormone therapy is a cancer treatment that removes hormones or blocks their action and stops cancer cells from growing. Hormones are substances produced by glands in the body and circulated in the bloodstream. Some hormones can cause certain cancers to grow. If tests show that the cancer cells have places where hormones can attach (receptors), drugs, surgery, or radiation therapy is used to reduce the production of hormones or block them from working.

Hormone therapy with drugs called corticosteroids may be used to treat thymoma or thymic carcinoma.

New drugs - researchers are currently studying several new treatments and treatment methods for patients with thymoma and thymic carcinoma. For patients with advanced thymoma or thymic carcinoma, several new drugs are being studied in clinical trials, including amrubicin, belinostat (Beleodaq), buparlisib, pembrolizumab (Keytruda), PHA-848125AC (milicilib), and saracatinib.

Multidisciplinary approach - a multidisciplinary approach to therapy for unresectable thymomas has been advocated. In one trial conducted by the MD Anderson Cancer Center, a treatment regimen consisting of induction chemotherapy (i.e., 3 courses of cyclophosphamide, doxorubicin, cisplatin, and prednisone), surgical resection, postoperative radiation therapy, and consolidation chemotherapy (i.e., 3 courses of cyclophosphamide, doxorubicin, cisplatin, and prednisone) was tested.

This study yielded encouraging results. Of 12 patients who underwent this treatment regimen, the disease had a complete response in 3 patients (25%), a partial response in 8 patients (67%), and a minor response in 1 patient (8%). Among 11 of these 12 patients (1 refused surgery), 9 (82%) had complete resections, and 2 (18%) who had been receiving radiation therapy and consolidation chemotherapy had incomplete resections. All 12 patients (100%) are alive at 7 years, and 10 of these patients (73%) are disease-free at 7 years. Therefore, the authors suggest that aggressive multimodal treatment is effective and may be curative in locally advanced, unresectable, malignant thymomas.

A study was conducted by Loehrer et al evaluating the effects of octreotide alone or with prednisone in 38 patients with advanced thymomas that expressed somatostatin receptors (i.e., that were octreotide scan positive). The patients were given 0.5 mg subcutaneously 3 times daily. Four (10.5%) of the 38 patients had a partial response with octreotide treatment alone. In the 21 patients in whom prednisone (0.6 mg/kg daily) was added, 2 complete and 6

partial responses (38%) occurred. Combination therapy resulted in better progression-free survival than octreotide therapy alone. Octreotide therapy may be a valuable treatment to use in cases in which chemotherapy is ineffective.
(Fox Chase Cancer Center; Medscape; Cleveland Clinic; Cancer.net).

Survival Rates for Thymoma and Thymic Carcinoma
International survival rates for Thymoma and Thymic Carcinoma are as follows:

Thymoma	**Five-year Survival Rate**	**Thymic**
Stage I	74%	Stage I
Stage II	73%	Stage II
Stage III	64%	Stage III
Stage IV	45%	Stage IV

(Cancer.net).

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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