

Clinical Trials – Klinische Studien

Clinical Trials in General

Clinical trials are the backbone of medical research. A current list of Beta Glucan clinical studies is listed further down this page. The studies listed are in various stages of evaluation and may take years to complete. Beta Glucan is one of the most studied treatment therapies, as a standalone treatment, in conjunction with other therapies to determine the efficacy of improved outcomes, as an immune system booster, and as a prophylactic treatment (improve treatment outcome by using BEFORE a surgical treatment). A clinical study involves research using human volunteers (also called participants) that is intended to add to medical knowledge. There are two main types of clinical studies: clinical trials and observational studies. ClinicalTrials.gov includes both interventional and observational studies.

Interventional Studies

In a clinical trial (also called an interventional study), participants receive specific treatments according to the research plan or protocol created by the investigators. These treatments may be medical products, such as drugs or devices; procedures; or changes to participants' behavior, for example, diet. Clinical trials may compare a new medical approach to a standard one that is already available or to a placebo that contains no active ingredients or to no comparable treatment.

Some clinical trials compare interventions that are already available to each other. When a new product or approach is being studied, it is not usually known whether it will be helpful, harmful, or no different than available alternatives. The investigators try to determine the safety and efficacy of the intervention by measuring certain outcomes in the participants. For example, investigators may give a drug or treatment to participants who have high blood pressure to see whether their blood pressure decreases. Clinical trials used in drug development are sometimes described by phase. These phases are defined by the Food and Drug Administration (FDA).

Note: Some people who are not eligible to participate in a clinical trial may be able to get experimental drugs or devices outside of a clinical trial through an Expanded Access Program. See more information on expanded access from the National Library of Medicine.

Observational Studies

In an observational study, investigators assess health outcomes in groups of participants according to a protocol or research plan. Participants may receive treatments, which can include medical products, such as drugs or devices, or procedures as part of their routine medical care, but participants are not assigned to specific treatments by the investigator (as in a clinical trial). For example, investigators may observe a group of older adults to learn more about the effects of different lifestyles on cardiac health.

Every clinical study is led by a principal investigator, who is often a medical doctor. Clinical studies also have a research team that may include doctors, nurses, social workers, and other health care professionals. Clinical studies can be sponsored, or funded, by pharmaceutical companies, academic medical centers, voluntary groups, and other organizations, in addition to Federal agencies such as the National Institutes of Health, U.S. Department of Defense, and U.S. Department of Veterans Affairs. Physicians, health care providers, and other individuals can also sponsor clinical research. Clinical studies can take place in many locations, including hospitals, universities, doctors' offices, and community clinics. The location depends on who is conducting the study. The length of a clinical study varies, depending on what is being studied. Participants are told how long the study will last before enrolling.

In general, clinical studies are designed to add to medical knowledge related to the treatment, diagnosis, and prevention of diseases or conditions. Some common reasons for conducting clinical studies include:

- Evaluating one or more treatments (for example, drugs, medical devices, approaches to surgery or radiation therapy) for treating a disease, syndrome, or condition
- Finding ways to prevent the initial development or recurrence of a disease or condition. These can include medicines, vaccines, or lifestyle changes, among other approaches.
- Evaluating one or more treatments aimed at identifying or diagnosing a particular disease or condition
- Examining methods for identifying a condition or risk factors for that condition
- Exploring and measuring ways to improve the comfort and quality of life of people with a chronic illness through supportive care

biological response modifier (BRM)

The cells of the human body have a nucleus and specific receptors on the exterior of the cell wall. These receptors help facilitate communication between cells by creating chemical messengers known as cytokines, to mount an immune response to invaders like bacteria, viruses, fungi, and cells that have become abnormal (i.e. cancerous). Biological response modifiers are sugar molecules known as polysaccharides, or sugar and protein molecules known as glycoproteins, which interact with the receptors on immune cell walls.

The immune cells of the body which normally protect the body from non-self invaders can often have difficulty in identifying invaders which are "self", such as abnormal cell development, cancer, or other problems that evolve from our own cells. Biological Response Modifiers can attach to the bad cell's receptors and solicit a powerful immune response neutralizing potential diseases. Interferons and interleukins are types of cytokines that have been exploited to artificially modify the body's response to the presence of cancer cells and have been highly publicized in clinical trials.

Used with Beta Glucan and/or Resveratrol, cytokines perform better and faster than normal. Biological response modifiers can be created in the laboratory to perform in a specific manner, and be used to target specific disease. Biological Response Modifiers also occur naturally and can be found in plants, food, and other elements of the environment. Beta Glucans are natural occurring BRM's, and are sugars that are found in the cell walls of bacteria, fungi, yeasts, algae, lichens, plants, and such grains as oats and barley. They have no known toxicity, are proven to boost other treatment options, and make the ideal adjuvant treatment, promoting increased immune activity and faster recovery times.