HIV Clinical Trials

(updated May 2021)

AETC AIDS Education & Training Center Program New England

HIV Clinical Trials

This education packet is a curated compilation of resources on HIV clinical trials, as well as some general information about clinical trials.

The contents of this packet are listed below:

- HIV/AIDS Clinical Trials (HIVinfo)
- Ensayos Clínicos Sobre la Infección por el VIH-SIDA (HIVinfo)
- About the Clinical Trials Process (AIDS Clinical Trials Group)
- What Is a Clinical Study? (HIV Prevention Trials Network)
- Glossary of Common Terms (NIH)
- Glosario de Términos Comunes (Salud.NIH.gov)

You may wish to customize this packet to meet the needs or interests of particular groups, such as event participants, providers, patients, clients, or the general public. So please feel free to distribute all or part of this document as either a printout or PDF.

HIV/AIDS Clinical Trials

hivinfo.nih.gov/index.php/understanding-hiv/fact-sheets/hivaids-clinical-trials

HIV Overview

Last Reviewed: September 28, 2020

Key Points

- A clinical trial is a research study done to evaluate new medical approaches in people. HIV/AIDS clinical trials help researchers find better ways to prevent, detect, or treat HIV/AIDS.
- Examples of HIV/AIDS clinical trials underway include studies of new HIV medicines, studies of vaccines to prevent or treat HIV, and studies of medicines to treat infections related to HIV.
- The benefits and possible risks of participating in an HIV/AIDS clinical trial are explained to study volunteers before they decide whether to participate in a study.
- Use the ClinicalInfo clinical trial search to find HIV/AIDS studies looking for volunteer participants. Some HIV/AIDS clinical trials enroll only people who have HIV. Other studies enroll people who don't have HIV.

What is a clinical trial?

A clinical trial is a research study done to evaluate new medical approaches in people. New approaches can include:

- new medicines or new combinations of medicines
- new medical devices or surgical procedures
- new ways to use an existing medicine or device
- new ways to change behaviors to improve health

Clinical trials are conducted to determine whether new medical approaches are safe and effective in people.

What is an HIV/AIDS clinical trial?

HIV/AIDS clinical trials help researchers find better ways to prevent, detect, or treat HIV/AIDS. For example, all of the medicines used to treat HIV/AIDS in the United States were first studied in clinical trials.
Examples of HIV/AIDS clinical trials underway include:

- studies of new medicines to prevent or treat HIV
- studies of vaccines to prevent or treat HIV
- studies of medicines to treat infections related to HIV

Can anyone participate in an HIV/AIDS clinical trial?

It depends on the study. Some HIV/AIDS clinical trials enroll only people who have HIV. Other studies include people who don't have HIV.
Participation in an HIV/AIDS clinical trial may also depend on other factors such as age, gender, HIV treatment history, or other medical conditions.

What are the benefits of participating in an HIV/AIDS clinical trial?

Participating in an HIV/AIDS clinical trial can provide benefits. For example, many people participate in HIV/AIDS clinical trials because they want to contribute to HIV/AIDS research. They may have HIV or know someone who has HIV.

People with HIV who participate in an HIV/AIDS clinical trial may benefit from new HIV medicines before they are widely available. HIV medicines being studied in clinical trials are called investigational drugs. To learn more, read the ClinicalInfo What is an Investigational HIV Drug? fact sheet.

Participants in clinical trials can receive regular and careful medical care from a research team that includes doctors and other health professionals. Often the medicines and medical care are free of charge.

Sometimes people get paid for participating in a clinical trial. For example, they may receive money or a gift card. They may be reimbursed for the cost of meals or transportation.

Are HIV/AIDS clinical trials safe?

Researchers try to make HIV/AIDS clinical trials as safe as possible. However, volunteering to participate in a study that is testing an experimental treatment for HIV can involve risks of varying degrees. Risks can include unpleasant, serious, or even life-threatening side effects from the treatment being studied.
Before enrolling in a clinical trial, potential volunteers learn about the study in a process called informed consent. The process includes an explanation of the possible risks and benefits of participating in the study.

Once enrolled in a study, people continue to receive information about the study through the informed consent process.

If I decide to participate in an HIV/AIDS clinical trial, will my personal information be shared?

The privacy of study volunteers is important to everyone involved in an HIV/AIDS clinical trial. The informed consent process includes an explanation of how a study volunteer's personal information is protected.

How can I find an HIV/AIDS clinical trial looking for volunteer participants?

To find an HIV/AIDS clinical trial call an HIVinfo health information specialist at 1-800-448-0440 or email ContactUs@HIVinfo.NIH.gov

This fact sheet is based on information from the following sources:

Provided in collaboration with NIH's Office of Aids Research.

Ensayos clínicos sobre la infección por el VIH/SIDA

hivinfo.nih.gov/index.php/es/understanding-hiv/fact-sheets/ensayos-clinicos-sobre-la-infeccion-por-el-vihsida

Visión general de la infección por el VIH

Última revisión: October 6, 2020

Puntos importantes

- Un ensayo clínico es un estudio de investigación realizado para evaluar nuevas formas de intervención médica destinadas al ser humano. Los ensayos clínicos sobre la infección por el VIH/SIDA ayudan a los investigadores a encontrar mejores formas de prevenir, detectar o tratar la infección por el VIH/SIDA.
- Entre los ejemplos de ensayos clínicos en curso sobre la infección por el VIH/SIDA cabe citar estudios de nuevos medicamentos contra el VIH, estudios de vacunas para prevenir o tratar la infección causada por ese virus y estudios de medicamentos para tratar las infecciones relacionadas con el mismo.
- Se explican los beneficios y posibles riesgos de la participación en un ensayo clínico sobre la infección por el VIH/SIDA a los voluntarios antes de que decidan participar o no en un estudio.
- Emplee el enlace de búsqueda de ensayos clínicos de ClinicalInfo para encontrar estudios sobre la infección por el VIH/SIDA que buscan participantes voluntarios. En algunos ensayos clínicos sobre este campo se inscriben solo a personas seropositivas (que tienen el virus). En otros se inscriben a personas seronegativas (que no tienen el virus).

¿Qué es un ensayo clínico?

Un ensayo clínico es un estudio de investigación que se realiza para evaluar nuevos métodos de atención médica, entre los cuales cabe citar:

- estudios de nuevos medicamentos para prevenir o tratar la infección por el VIH,
- nuevos dispositivos médicos o procedimientos quirúrgicos,
- nuevas formas de empleo de un medicamento o dispositivo existente,
- nuevas formas de cambiar el comportamiento para mejorar la salud.

Los ensayos clínicos se realizan para determinar si los nuevos métodos de atención médica son seguros y eficaces para la población destinataria.

¿Qué es un ensayo clínico sobre la infección por el VIH/SIDA?

Los ensayos clínicos sobre la infección por el VIH/SIDA ayudan a los investigadores a encontrar mejores formas de prevención, detección o tratamiento. Por ejemplo, todos los medicamentos empleados para tratar dicha infección en los Estados Unidos se han estudiado primero en ensayos clínicos.

Entre los ejemplos de ensayos clínicos en curso sobre la infección por el VIH/SIDA cabe citar:

- estudios de nuevos medicamentos para tratar la infección por el VIH
- estudios de vacunas para prevenir o tratar la infección por el VIH
- estudios de medicamentos para tratar las infecciones relacionadas con el VIH

¿Puede cualquier persona participar en un ensayo clínico sobre la infección por el VIH/SIDA?

Depende del estudio. En algunos ensayos clínicos sobre la infección por el VIH/SIDA se inscriben solamente personas seropositivas (que tienen el virus). En otros se incluyen a personas seronegativas (que no tienen el virus).

La participación en un ensayo clínico sobre la infección por el VIH/SIDA también puede depender de otros factores, como la edad, el sexo, los antecedentes de tratamiento de la infección por el VIH y otras afecciones médicas de una persona.

¿Cuáles son los beneficios de participar en un ensayo clínico sobre la infección por el VIH/SIDA?

La participación en un ensayo clínico sobre la infección por el VIH/SIDA puede reportar beneficios. Por ejemplo, muchas personas participan en estos ensayos clínicos porque desean contribuir a las investigaciones sobre ese campo. Es posible que sean seropositivas o que conozcan a alguien que lo sea.

Las personas seropositivas que participan en un ensayo clínico sobre la infección por el VIH/SIDA pueden beneficiarse de nuevos medicamentos contra ese virus antes de que estén a disposición del público. Los medicamentos contra el VIH objeto de estudio en ensayos clínicos se llaman medicamentos en fase de investigación. Para mayor información, lea la hoja informativa de *info*SIDA titulada ¿Qué es un medicamento contra el VIH en fase de investigación?

Los participantes en ensayos clínicos pueden recibir atención médica regular y cuidadosa del equipo de investigación formado por médicos y otros profesionales de salud. A menudo, los medicamentos y la atención médica son gratuitos.

A veces, se les paga a los participantes en un ensayo clínico. Por ejemplo, pueden recibir dinero o una tarjeta de regalo. Se les puede reembolsar el costo de las comidas o del transporte.

¿Son seguros los ensayos clínicos sobre la infección por el VIH/SIDA?

Los investigadores tratan de lograr que los ensayos clínicos sobre la infección por el VIH/SIDA sean seguros al máximo posible. Sin embargo, el hecho de ofrecerse como voluntario para participar en un estudio de prueba de un tratamiento experimental de la infección por el VIH puede acarrear riesgos de diversos grados. Los riesgos pueden comprender efectos secundarios desagradables, graves o aun potencialmente mortales, causados por el tratamiento objeto de estudio.

Antes de inscribirse en un ensayo clínico, los futuros voluntarios obtienen información sobre el estudio en un proceso llamado consentimiento informado. El proceso incluye una explicación de los posibles riesgos y beneficios de la participación en el estudio.

Una vez inscritas en el estudio, las personas siguen recibiendo información sobre el mismo por medio del proceso de consentimiento informado.

Si decido participar en un ensayo clínico sobre la infección por el VIH/SIDA, ¿se compartirá mi información personal?

La privacidad de los voluntarios del estudio es importante para todos los participantes en un ensayo clínico sobre la infección por el VIH/SIDA. El proceso de consentimiento informado incluye una explicación sobre la forma en que se protege la información personal de cada voluntario.

¿Cómo puedo encontrar un ensayo clínico sobre la infección por el VIH/SIDA para el cual se busquen participantes voluntarios?

Para encontrar un ensayo clínico sobre llame a un especialista en información de salud de HIVinfo al teléfono 1-800-448-0440 o envíe un correo electrónico a ContactUs@HIVinfo.NIH.gov.

La hoja informativa precedente se basa en la correspondiente en inglés.

Proporcionado en colaboración con la Oficina de Investigación del SIDA de los NIH

About the Clinical Trials Process

actgnetwork.org/faq

Interested in learning more about clinical trials? This Q&A can help explain how these trials work, how you can participate, and where you can get more information:

What is a clinical trial?

A clinical trial is a carefully designed research study in which a treatment or therapeutic process in development is tested in people. A clinical trial may vary in length from a few weeks to several years. HIV/AIDS clinical trials, the type run by the AIDS Clinical Trials Group (ACTG), are designed to answer specific questions about the safety and effectiveness of different treatments for HIV/AIDS and related conditions.

An ACTG clinical trial may study experimental medications to treat HIV and AIDS, or to prevent or treat HIV-related infections. ACTG studies may also look at a possible new use for a medication that has already been tested and government-approved, or may study ways to help people manage their HIV/AIDS medications or long-term general health.

Why do researchers conduct clinical trials?

Clinical trials are the gold standard of modern medicine. They are the only direct way to learn how different people respond to medications, treatments, or therapeutic approaches. All treatments for HIV/AIDS and related conditions must be tested through clinical trials before they can be approved. HIV/AIDS clinical trials provide critical information to help people living with HIV to live longer, healthier lives.

How do clinical trials work?

All ACTG clinical trials are subject to extensive review. Detailed study plans, also known as the study “protocol,” are reviewed extensively by research experts and ethicists. Each clinical trial is also reviewed by an Institutional Review Board (IRB), a diverse group of experts that must approve the trial. The IRB also reviews ongoing clinical trial operations periodically to ensure that the study is being conducted properly, that any risks from participating are as low as possible, and that any risks are outweighed by the potential benefits of the study.

To ensure reliable results, clinical trials follow precise research plans called protocols. The protocol describes every aspect of a research study, including the study timeline and processes and what question or questions the study hopes to answer.

The clinical trial process generally follows four key phases. A study can be either a Phase 1, 2, 3 or 4 trial, depending on where the treatment being studied is in its development.

- Phase 1 Trials: Provide a study medication to a small group of people for the first time, to measure its safety.
- Phase 2 Trials: Provide a study medication to larger groups of people to see if it works and to further evaluate its safety.
- Phase 3 Trials: Provide a study medication to very large groups of people to develop information that will allow the drug to be marketed and used safely.
- Phase 4 Trials: Provide additional information about the study medication after it has been approved for marketing

Who sponsors clinical trials?

HIV/AIDS clinical trials are developed by the AIDS Clinical Trials Group (ACTG) protocol team members and supported by pharmaceutical companies. The National Institutes of Health (National Institute of Allergy and Infectious Diseases, Division of AIDS) sponsors the ACTG clinical trials network.

Can anyone participate in a clinical trial?

Different clinical trials have different requirements, or criteria, for their participants. When selecting participants, researchers may consider a number of factors, which can include the participant's age, sex, health status (things like your CD4 or T-cell count, HIV viral load, past medical history, or medication history), and willingness and ability to follow the trial's instructions and schedules.

What are the potential benefits of participating in a clinical trial?

Study participants may be among the first people to receive a new experimental medication. Other benefits include receiving HIV/AIDS health care related to the research study by HIV-experienced physicians and study nurses, and helping others by adding to the medical information available about HIV/AIDS. The medications, clinic visits, evaluations, and laboratory tests required by the research study will usually be provided to participants free of charge. Medical information obtained during the clinical trial can be shared with your own health care provider.

What are the potential risks of participating in a clinical trial?

A study medication may not be helpful to you, or might cause harm, including side effects. Anyone considering participating in a clinical trial will receive full information on possible side effects from the study staff and in the study consent form. Participants may not be able to continue with their current treatments while in the study, and may not be able to continue receiving the tested drug after the study ends.

How is the safety of participants protected?

All ACTG clinical trials are subject to strict, mandatory safeguards that are designed to reduce any risks to study participants. Each clinical trial is reviewed, approved, and monitored by an Institutional Review Board (IRB). Some trials also have community advisory boards. In addition, all study participants must read and sign informed consent documents. These documents ensure that participants understand the risks and potential benefits of participating in the study, as well as their rights and responsibilities as study volunteers.

What is “informed consent?”

Anyone who wishes to join a clinical trial must understand everything about the study – including the potential risks and benefits and all of the obligations of participating. If an individual qualifies for a study and is interested in participating, the research staff will explain the study in detail and answer any questions the potential volunteer has. When the study has been fully explained and all questions have been answered, the participant will be asked to read and sign a document stating that they give their informed consent to participate in the study. The participant will receive a copy of the consent form.

What questions should you ask about the trial?

Anyone interested in participating in a clinical trial should feel free to ask any and all questions they have about the study, and to have all answers explained to them until they feel comfortable with the information. Questions that a potential participant might ask include:

- What is the purpose of the clinical trial?
- What will I need to do to join the clinical trial?
- Are there already-approved treatments available for my medical condition?
- How do the treatments used in this study compare with any available treatments?
- Will I know what drug I am taking in the study?
- How often will I need to come to appointments, use study medications, and have medical tests?
- What side effects might I experience if I participate?
- What should I do if I experience side effects, feel uncomfortable, or have questions during the clinical trial?
- How will my confidentiality be protected?
- What kind of long-term follow up care will be provided as part of the clinical trial?
- Will there be any costs involved in participating?

How can I find out what clinical trials are open for enrollment?

A list of ACTG clinical trials currently open for enrollment is available here. The list is updated frequently, so please feel free to check back for updates.

Each study description includes a list of Participating Sites, so you can see if a study of interest is being conducted at a site near you, along with contact information for each study site. The site contact person can provide you with any information you need about studies

they are conducting. Your conversation will be completely confidential. You do not need to give your name or phone number to receive this information.

What is a screening visit?

If you are interested in and potentially eligible for a study, you will be invited to make an appointment for a screening visit at the clinic. The study staff may ask you to bring your medical records, including HIV-related and other significant medical history, HIV medication history, and recent laboratory results.

During the screening visit, the study will be reviewed in detail and you will have an opportunity to ask any questions. If you decide to participate, the study nurse will review a consent form with you and ask you to sign the form to give permission to proceed with the screening evaluations. In most screening visits, blood samples will be drawn and you will be examined by the study doctor to determine whether you meet the study eligibility criteria.

What happens during the clinic trial?

If screening tests show that you qualify to enter the study, the study nurse will schedule an entry visit. Lab tests will be done to get baseline values, and you will receive your study medication. During this visit the study medication dosing will be reviewed with you and you will receive information about possible side effects and phone numbers to call with questions or problems.

The frequency of your visits to the clinic will depend on the study. Most follow-up visits consist of a brief physical exam, lab tests, and a review of your study medications.

Will my primary care physician receive information about the clinical trial?

The clinical research staff will be in close communication with your physician. Your physician will receive copies of the lab results obtained through the study. The study staff will also contact them if you have any trouble with the study medication to discuss management and any changes needed in your study medication.

What is a Clinical Study?

hptn.org/community/community-educational-resources/what-is-a-clinical-study

A clinical study involves either observational research or research that studies medical, surgical, or behavioral interventions in people, often called a clinical trial. They are the primary way researchers conclude if a new treatment, like a new drug, is safe and effective in people.

In the HPTN's HIV prevention clinical studies, we examine use of antiretroviral drugs (antiretroviral therapy and pre-exposure prophylaxis); interventions for substance abuse, particularly injection drug use; behavioral risk reduction interventions, and structural interventions.

There are four phases of clinical studies.

Phase 1 Clinical Studies

Phase I studies test the safety of a product. This means seeing if there are side effects, and whether the human body can tolerate the experimental product, such as a new drug. This product is often compared to a group that receives a placebo, a substance such as sterile saltwater that has no active ingredients. These studies are conducted with a small group of people (usually less than 100) and typically last 12 to 18 months.

Phase 2 Clinical Studies

Phase 2 studies look at questions such as the maximum tolerated dose of a product, the optimal schedule for giving the product (how many doses, and at what time intervals), and whether the immune system is having the desired responses. These responses can include

the production of antibodies, the production of T cells, and other immune system markers. These studies are conducted with a medium-size population of volunteers (usually a few hundred to 1,000) and the studies can last up to two years.

Phase 2b Clinical Studies

Phase 2b studies are a way to get an early look at whether the product is effective at preventing infection or disease. They are sometimes known as Proof of Concept or Test of Concept studies. A group of several thousand people who are at increased risk for infection or disease are enrolled, and the studies can last about 2-5 years. Based on the data from these studies, researchers can see whether the results seem favorable, supporting moving ahead to Phase 3. If the results are less favorable, it means that researchers can redirect their efforts and save the expenses of large Phase 3 studies.

Phase 3 Clinical Studies

Phase 3 studies are where researchers can ask the questions, “Does this product prevent new infections?” Or “if people do become infected, does the product help them control the infection so that it doesn’t become severe disease?” These studies involve many thousands of people, usually including some participants who are at increased risk for infection.

Phase 4 Clinical Studies

Phase 4 studies may take place after a product has been found to be effective in some populations and are utilized to gather additional information about safety and effectiveness by testing the product in additional populations such as children or pregnant women. They are sometimes known as bridging studies, or post-licensure studies. These studies may be conducted in anyone seeking a prevention option from their physician.

Glossary of Common Terms | National Institutes of Health (NIH)

nih.gov/health-information/nih-clinical-research-trials-you/glossary-common-terms

May 14, 2015

Clinical Research

Clinical research is medical research that involves people to test new treatments and therapies.

Clinical Trial

A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

Healthy Volunteer

A Healthy volunteer is a person with no known significant health problems who participates in clinical research to test a new drug, device, or intervention.

Inclusion/Exclusion Criteria

Inclusion/Exclusion Criteria are factors that allow someone to participate in a clinical trial are *inclusion criteria*. Those that exclude or not allow participation are *exclusion criteria*.

Informed Consent

Informed consent explains risks and potential benefits about a clinical trial before someone decides whether to participate.

Patient Volunteer

A patient volunteer has a known health problem and participates in research to better understand, diagnose, treat, or cure that disease or condition.

Phases of Clinical Trials

Clinical trials are conducted in “phases.” The trials at each phase have a different purpose and help researchers answer different questions.

- **Phase I trials** — An experimental drug or treatment in a small group of people (20–80) for the first time. The purpose is to evaluate its safety and identify side effects.

- **Phase II trials** — The experimental drug or treatment is administered to a larger group of people (100–300) to determine its effectiveness and to further evaluate its safety.
- **Phase III trials** — The experimental drug or treatment is administered to large groups of people (1,000–3,000) to confirm its effectiveness, monitor side effects, compare it with standard or equivalent treatments.
- **Phase IV trials** — After a drug is licensed and approved by the FDA researchers track its safety, seeking more information about its risks, benefits, and optimal use.

Placebo

A placebo is a pill or liquid that looks like the new treatment but does not have any treatment value from active ingredients.

Protocol

A Protocol is a carefully designed plan to safeguard the participants' health and answer specific research questions.

Principal Investigator

A Principal Investigator is a doctor who leads the clinical research team and, along with the other members of the research team, regularly monitors study participants' health to determine the study's safety and effectiveness.

Randomization

Randomization is the process by which two or more alternative treatments are assigned to volunteers by chance rather than by choice.

Single- or Double-Blind Studies

Single- or double-blind studies (also called single- or double-masked studies) are studies in which the participants do not know which medicine is being used, so they can describe what happens without bias.

Types of Clinical Trials

- **Diagnostic trials** determine better tests or procedures for diagnosing a particular disease or condition.
- **Natural history studies** provide valuable information about how disease and health progress.
- **Prevention trials** look for better ways to prevent a disease in people who have never had the disease or to prevent the disease from returning.
- **Quality of life trials** (or supportive care trials) explore and measure ways to improve the comfort and quality of life of people with a chronic illness.

- **Screening trials** test the best way to detect certain diseases or health conditions.
- **Treatment trials** test new treatments, new combinations of drugs, or new approaches to surgery or radiation therapy.

This page last reviewed on February 10, 2016

Glosario de términos comunes

Investigación clínica

La investigación clínica es la investigación médica en la que participan personas como usted para evaluar nuevos tratamientos y terapias.

Voluntario sano

Un voluntario sano es una persona sin problemas serios de salud que participa en una investigación clínica para evaluar un nuevo medicamento, dispositivo, aparato médico, o intervención.

Criterios de inclusión/exclusión

Las características que permiten que alguien participe en un estudio clínico son los *criterios de inclusión*. Las características que no permiten que alguien participe en un estudio clínico son los *criterios de exclusión*.

Consentimiento informado

El consentimiento informado es el proceso que proporciona a los posibles participantes los datos más importantes de un estudio clínico antes de que decidan si desean participar o no.

Paciente voluntario

Un paciente voluntario es una persona que presenta un problema de salud conocido y participa en la investigación para comprender, diagnosticar, tratar mejor o curar su enfermedad o trastorno.

Fases de los estudios clínicos

Los estudios clínicos se realizan en “fases”. Cada fase tiene un objetivo diferente y ayuda al científico a contestar distintas preguntas.

- **Estudios en fase I:** Los investigadores evalúan un medicamento o tratamiento experimental por primera vez en un grupo de personas pequeño (20 a 80). El objetivo es evaluar su seguridad y conocer los efectos secundarios.
- **Estudios en fase II:** Se administra el tratamiento o medicamento experimental a un grupo de personas más grande (100 a 300) para determinar su efectividad y continuar evaluando su seguridad.

- **Estudios en fase III:** Se administra el medicamento o tratamiento experimental a un grupo de personas aún más grande (1000 a 3000) para confirmar su efectividad, supervisar los efectos secundarios, compararlo con los tratamientos estándar o equivalentes y obtener información para que el tratamiento o medicamento experimental se use de manera segura.
- **Estudios en fase IV:** Después de que un medicamento es aprobado por la Administración de Alimentos y Medicamentos (FDA , por sus siglas en inglés) y se ofrece al público, los investigadores hacen un seguimiento de su seguridad para buscar más información sobre los riesgos, los beneficios y el mejor uso de un medicamento o tratamiento.

Placebo

Placebo es un producto inactivo que se parece al producto experimental, pero que no tiene la misma acción terapéutica. Se utiliza en algunos estudios clínicos para comprobar la efectividad del producto experimental.

Protocolo

El protocolo es un plan en el que se basa un estudio clínico. El protocolo se diseña con cuidado para proteger la salud de los participantes y contestar preguntas específicas acerca de la investigación.

Investigador principal

Un Investigador principal es por lo general, un médico que dirige el equipo de investigación clínica y quien, junto con los demás miembros del equipo de investigación, supervisa la salud de los participantes durante el estudio para determinar que este es seguro y efectivo.

Aleatorización

La aleatorización es el es el proceso para asignar al azar, y no por elección, a los voluntarios para que reciban dos o más tratamientos alternativos.

Estudios simples o doble ciegos

En estudios simples o doble ciegos, también conocidos como estudios de enmascaramiento simple o doble, los participantes no saben qué medicamento se utiliza, para que puedan describir lo que sucede sin ninguna predisposición.

Tipos de estudios clínicos

- Los **estudios de historia natural** brindan información valiosa sobre cómo evolucionan la enfermedad y la salud.

- Los **estudios de prevención** buscan mejores maneras de prevenir una enfermedad en personas que nunca la han tenido o de evitar que la enfermedad regrese. Estas maneras pueden incluir medicamentos, vacunas o cambios en el estilo de vida, entre otras cosas.
- Los **estudios de detección** evalúan la mejor manera de detectar determinadas enfermedades o trastornos.
- Los **estudios de diagnóstico** determinan las mejores pruebas o procedimientos para diagnosticar una enfermedad o un trastorno.
- Los **estudios de tratamiento** evalúan nuevos tratamientos, nuevas combinaciones de medicamentos o nuevos enfoques para la cirugía o la radioterapia.
- Los **estudios de calidad de vida** (o estudios de cuidados complementarios) exploran y evalúan cómo mejorar la comodidad y la calidad de vida de las personas que tienen una enfermedad crónica.

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