



Clinical Trials



New drugs and treatments that show the most promise in a laboratory setting may be moved into a clinical trial. The goal of a clinical trial is to assess the safety and effectiveness of the new therapy. Clinical trials offer hope for many people and provide an opportunity to help researchers find better treatments. Current trials are evaluating a range of outcomes important to the SCI community from enhanced mobility to autonomic recoveries.

Q: What happens during a clinical trial?

Led by a principal investigator (PI), who is often a doctor, clinical trials follow specific protocols that describe who is eligible, length of study, and information gathered, as well as the trial's objective, design and approach used. Clinical research usually begins with a small number of participants and becomes progressively larger over time. Each of the four regulated phases of a clinical trial answers important questions

and provides evidence required to receive U.S. Food and Drug Administration (FDA) approval.

Phase I: evaluates the safety and potential side effects in a small group of people (20-80).

Phase II: expands to a larger group (100-300) at several centers to test safety and efficacy on a broader scale and evaluate different dosing amounts or treatment techniques.

Phase III: increases the number of centers and participants (1,000-3,000) who are then divided into two double-blind, randomized groups. Doctors and participants do not know their trial group details, so results can be compared and confirmed on an unbiased basis. Success in Phase III leads to approval by the FDA for clinical use.

Phase IV: continues to track the FDA-approved treatment's safety, risks, benefits, and optimal use as it becomes available for public use.

Be aware that drugs or treatments may not be available to you after the trial is over. The drug or therapy may fail in trial and never make it to market or it may be successful but not available until it has FDA approval which can take years.

Important Questions to Consider When Applying for a Clinical Trial

- Why is this research being done, what is the goal of the trial, and who is sponsoring it?
- How do the possible risks and benefits compare with approved treatments for me?
- What are the possible immediate and long-term side effects?
- What phase is the trial in?
- Will I have to pay for travel or lodging to participate in the study?
- If I participate in an early phase of the trial, will I be eligible to participate in later phases?

Source: National Institutes of Health

Q: How can I participate in a clinical trial?

As promising research continues to expand, there are many clinical trials in development and underway in the U.S. and around the world. There is no cost to participate and no payment or stipend is offered to avoid influencing potential results. All participants must meet specific eligibility guidelines based on factors such as age, type of disease, medical history, and current medical condition. A database of worldwide privately and publicly funded clinical trials can be found at clinicaltrials.gov.

Q: What is informed consent?

If you are considering joining a clinical trial, the research staff will give you informed

consent documents that describe the trial's purpose, duration, risks, benefits, possible side effects, required procedures, and who to contact for further information. Informed consent continues as long as you are in the study, but it is not a contract. Participants are free to withdraw from the study at any time, or to refuse particular treatments or tests.

Q: Are clinical trials supervised?

The U.S. government has strict safeguards to protect people who participate in clinical trials. Every clinical trial in the U.S. must be approved and monitored by an Institutional Review Board (IRB) to make sure the risks are as low as possible and are worth any potential benefits. An IRB is an independent committee of physicians, statisticians, community advocates, and others that ensures a clinical trial is ethical and the rights of study participants are protected.

Q: Are there any advantages to going overseas for treatment if I can't get that treatment in the U.S.?

Be very cautious before joining a trial outside the jurisdiction of the FDA (the FDA covers the United States) or seeking an unproven or experimental treatment. Legitimate clinical trials never charge patients to participate. Any human clinical trial must, at minimum, adhere to the international guideline of the Declaration of Helsinki and the standards of the host country. Although the cost-savings from using a foreign medical treatment can be tempting, it may not outweigh the risks.

Q: What is the difference between a clinical trial and human experiments?

The investigator for a registered clinical trial should have immediate and detailed study information available. There should be no cost to participate and you should remain blind to whether you are in the experimental or control group of the study. While clinical trials are required to follow strict ethical and procedural protocols, human experiments may not abide by adequate measures to minimize risk and protect volunteer rights

Sources: Food and Drug Administration

Need to talk to someone?

Our Information Specialists are available to answer your questions.

Call toll-free 1-800-539-7309 Mon-Fri, 9am-5pm ET.

Or [schedule a call](#) or [ask a question online](#).

Resources for Clinical Trials

General Information:

Christopher & Dana Reeve Foundation: Clinical Trials

For information on the epidural stimulation research trial at the University of Louisville, please see <http://www.ReeveBigIdea.org>. You can access the registry to participate in research at the University of Louisville at <https://victoryoverparalysis.org/participate-in-research>.

In 2017, the Food and Drug Administration approved a clinical trial on epidural stimulation of individuals with spinal cord injury at the University of Louisville. The [clinical trial](#) is sponsored by the Reeve Foundation. Please also see a list of Frequently Asked Questions about the epidural stimulation clinical trial at <https://www.christopherreeve.org/blog/daily-dose/the-big-idea-your-top-questions-answered>.

Food and Drug Administration: Clinical Trials: What Patients Need to Know

<https://www.fda.gov/patients/clinical-trials-what-patients-need-know>

Froedtert & Medical College of Wisconsin: Clinical Trials Basics

<https://www.froedtert.com/research/clinical-trials/basics>

Phone: 914-805-3000

ICORD: Clinical Trials Information

<http://icord.org/research/iccp-clinical-trials-information/>

Phone: 604-875-4992

International Campaign for Cures of Spinal Cord Injury Paralysis (ICCP): Experimental Treatments for Spinal Cord Injury: What You Should Know if You Are Considering Participation in a Clinical Trial. 2nd version 2012. Full report

<http://icord.org/wp-content/uploads/2012/09/FINAL-Version-2-Experimental-Treatments-for-SCI-locked.pdf>

MedlinePlus: Clinical Trials

<https://medlineplus.gov/clinicaltrials.html>

Multiple Sclerosis Association of America: Clinical Trials Search Tool

<https://mymsaa.org/ms-information/clinical-trials-search/>

Phone: 800-532-7667

Allows one to search for MS related clinical trials by geographic location and a few other filters.

National Institute on Aging: Clinical Trials and Older Adults

<https://order.nia.nih.gov/publication/clinical-trials-and-older-adults-easy-to-read-booklet>

Read the booklet online or place an order for a free copy.

NIH Clinical Research Trials and You

<https://www.nih.gov/health-information/nih-clinical-research-trials-you>

An NIH-hosted website for patients thinking about participating in a clinical trial.

WebMD: Clinical Trials: A Guide for Patients

<https://www.webmd.com/a-to-z-guides/clinical-trial-guide-patients>

Databases of Clinical Trials:**CenterWatch**

<https://www.centerwatch.com/>

300 N. Washington St., Suite 200

Falls Church, VA 22046

Phone: 617-948-5100, 866-219-3440 (Toll-free)

E-mail: customerservice@centerwatch.com

CenterWatch's website has a wealth of information related to clinical trials and is designed to be a resource for both patients interested in participating in clinical trials and for research professionals. CenterWatch is a division of the Thomson Corporation.

ClinicalTrials.gov

<https://www.clinicaltrials.gov/>

ClinicalTrials.gov offers general information on clinical trials and specific information on federally and privately supported clinical trials (conducted in the United States and around the world) for a wide range of diseases and conditions. The website provides information about a trial's purpose, eligible participants, locations, and contacts. ClinicalTrials.gov also has a results database that reports summary results of registered clinical trials and observational studies.

Health Canada: Clinical Trials Database

<https://health-products.canada.ca/ctdb-bdec/?lang=eng>

Health Canada, through its Clinical Trials Database, is providing to the public a listing of specific information relating to phase I, II and III clinical trials in patients. The database is managed by Health Canada and provides a source of information about Canadian clinical trials involving human pharmaceutical and biological drugs.

ISRCTN Registry

<https://www.isrctn.com/>

c/o BioMed Central

The Campus, 4 Crinan St.

London, N1 9XW

United Kingdom

Email: info@biomedcentral.com

ISRCTN is a registry and curated database containing the basic set of data items deemed essential to describe a study at inception, as per the requirements set out by the World Health Organization (WHO) International Clinical Trials Registry Platform (ICTRP) and the International Committee of Medical Journal Editors (ICMJE) guidelines. All study records in the database are freely accessible and searchable and have been assigned an ISRCTN ID.

SCITrialsFinders.net

<https://scitrialsfinder.net/>

This site lets people find SCI trials in their area.

Spinal Cord Injury Trials: Connecting Scientists and the SCI Community

<https://scitrials.org/>

Provides a search mechanism for SCI trials that can be filtered by level of injury, time since injury, severity of injury, and geographic location.

Spinal Cord Injury Information Network: Research

<https://www.uab.edu/medicine/sci/research>

The Spinal Cord Injury Information Network's page on research studies provides information on studies at the University of Alabama at Birmingham's Spain Rehabilitation Center and elsewhere.

World Health Organization: International Clinical Trials Registry

<https://www.who.int/clinical-trials-registry-platform>

The World Health Organization's searchable database of clinical trials registered in various countries.

Research Centers and Programs:

Department of Veterans Affairs (VA): Cooperative Studies Program

<https://www.research.va.gov/programs/csp/>

The VA Cooperative Studies Program conducts research studies, including multicenter clinical trials and epidemiological studies, in collaboration with other federal, international, university, and private industry partners.

International Campaign for Cures of Spinal Cord Injury Paralysis (ICCP): Experimental Treatments for SCI

https://asia-spinalinjury.org/wp-content/uploads/2016/02/Experimental_Treatments_for_SCI.pdf

Non-profit organizations affiliated with ICCP work to fund research into cures for paralysis caused by spinal cord injury. The website provides information on spinal cord injury research.

International Center for Spinal Cord Injury (ICSCI) at Kennedy Krieger Institute

https://www.kennedykrieger.org/patient-care/centers-and-programs/international-center-for-spinal-cord-injury?gclid=EAlalQobChMli5jE_vnr6QIVF5SzCh08Rgr8EAAYASAAEgLYvPD_BwE

707 North Broadway

Baltimore, MD 21205

Phone: 443-923-9400 (Local Referral); 888-554-2080 (Toll-free Referral)

TTY: 443-923-2645

E-mail: info.sci@spinalcordrecovery.org

The ICSCI focuses on restoration and rehabilitation for children and adults with chronic paralysis. Research includes activity based restorative therapies which are designed to

help individuals with spinal cord injury recover sensation, function, and mobility.

Miami Project to Cure Paralysis

<https://www.themiamiproject.org/research/>

1095 NW 14th Terrace

Lois Pope Life Center

Miami, FL 33136

Phone: 305-243-6001 or 800-STAND UP

Email: miamiproject@med.miami.edu

The Miami Project's international team is housed in the Lois Pope LIFE Center and includes more than 300 scientists, researchers, clinicians and support staff who take innovative approaches to the challenges of brain and spinal cord injury. The Miami Project's Christine E. Lynn Clinical Trials Initiative is designed to take discoveries found to be successful in laboratory studies and fast track them to human studies. Their FDA approved Schwann cell transplantation trial, the only one of its kind in the world, is changing the spinal cord injury field and sets an important foundation for future Miami Project cell replacement therapies.

Miami Project researchers are conducting or participating in more than ten clinical trials for spinal cord and brain injuries and have more than a dozen clinical research studies underway. Because of our clinical and research expertise, The Miami Project is confident that we have the knowledge and resolve to initiate additional clinical trials that help us to continue to responsibly and safely take these important steps into humans.

Reeve-Irvine Research Center

<https://www.reeve.uci.edu/>

College of Medicine, University of California, Irvine

2107 Gillespie Neuroscience Research Facility

Irvine, CA 92697-4265

Phone: 949-824-0210

E-mail: rirc@uci.edu

The Reeve-Irvine Research Center has been established to study injuries to and diseases of the spinal cord that result in paralysis or other loss of neurologic function, with the goal of finding a cure. Named for actor Christopher Reeve, the Center is part of the College of Medicine of the University of California, Irvine. The Reeve-Irvine Research Center is located in the Gillespie Neuroscience Research Facility and is led by Dr. Oswald Steward. Activities under the Center's auspices promote the coordination and cooperation of scientists around the world seeking a cure for paraplegia and quadriplegia and amelioration of diseases impacting neurological function.

Shepherd Center Research

<https://www.shepherd.org/resources-healthcare-professionals/research>

2020 Peachtree Road NW

Atlanta, GA 30309-1465

Phone: 404-352-2020

Shepherd Center is a model SCI facility. Their research team develops and evaluates

new drugs, treatments, and therapy interventions in the SCI, TBI, and MS field. You can complete their intake form to be considered for research participation.

The information contained in this message is presented for the purpose of educating and informing you about paralysis and its effects. Nothing contained in this message should be construed nor is intended to be used for medical diagnosis or treatment. It should not be used in place of the advice of your physician or other qualified health care provider. Should you have any health care related questions, please call or see your physician or other qualified health care provider promptly. Always consult with your physician or other qualified health care provider before embarking on a new treatment, diet or fitness program. You should never disregard medical advice or delay in seeking it because of something you have read in this message.

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