Clinical Trials

There is no central registry database for spinal cord injury (SCI) related clinical trials; however, there are several databases you can check to see if you might qualify for any clinical trials currently being conducted. Most of the following information can be found on the Reeve Foundation’s web site (https://www.christopherreeve.org/research/nactn/what-are-clinical-trials).

Before enrolling in a clinical trial, it is important to review the following information from the National Institute of Health (NIH):

**CLINICAL TRIALS**

Drugs and treatments are developed from laboratory experiments. Clinical research is usually conducted in a series of trials that become progressively larger. Carefully conducted clinical trials are the fastest and safest way to find treatments that work.

Once researchers test new therapies or procedures in the laboratory and get promising results, they begin planning Phase I clinical trials. New therapies are tested on people only after laboratory and animal studies show promising results.

A Phase I clinical trial is directly built upon basic and animal research and is primarily used to test the safety of a therapy for a particular disease or condition and to estimate possible usefulness in a few human subjects.

A Phase II clinical trial usually involves many subjects at several different centers and is used to test safety and efficacy on a broader scale, to test different dosing for medications or to perfect techniques for surgery, and to determine the best methodology for the bigger Phase III clinical trial to come.

A Phase III clinical trial often involves many centers and sometimes several hundred subjects. The trial usually has two patient groups who receive different treatments, but all other standard care is the same. The trial may compare two treatments, or, if there is only one treatment to test, patients who do not receive the test therapy receive instead a placebo (dummy drug).

Many Phase III trials are called double-blind, randomized clinical trials. Double-blind means that neither the subjects nor the doctors treating the subjects and determining the response to the therapy know which treatment a subject receives. Randomization refers to the placing of subjects
into one of the treatment groups in a way that can't be predicted by the patients or investigators. These clinical trials usually involve many investigators and take many years to complete.

Most treatments for general use come out of Phase III clinical trials. After one or more phase III trials are finished, and if the results are positive for the treatment, the investigators can petition the FDA for government approval to use the drug or procedure to treat patients. Once the FDA approves the treatment, doctors throughout the country can prescribe it.

**PROTECTIONS FOR PEOPLE IN CLINICAL TRIALS**

The 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 that a clinical trial is ethical and the rights of study participants are protected.

**INFORMED CONSENT**

Informed consent is the process of learning the key facts about a clinical trial before you decide whether or not to participate. These facts include:

- Why the research is being done
- What the researchers want to accomplish
- What will be done during the trial and for how long
- What risks are involved in the trial
- What benefits can be expected from the trial
- What other treatments are available
- The fact that you have the right to leave the trial at any time

If you are considering joining a clinical trial, the research staff will give you informed consent documents that include the details about the study. Since joining a clinical trial is an important decision, you should ask the research team any questions you may have about the study and the consent forms before you make a decision.

Remember informed consent is more than signing a form. It is a process that continues through the study. You should feel free to ask the research team questions before, during, and after the study. Informed consent continues as long as you are in the study.

**WHO CAN PARTICIPATE IN A CLINICAL TRIAL?**

All clinical trials have guidelines about who can get into the program. Guidelines are based on such factors as age, type of disease, medical history, and current medical condition. Before you join a clinical trial, you must qualify for the study. Some research studies seek volunteers with illnesses or conditions to be studied in the clinical trial, while others need healthy volunteers. Healthy volunteers participate in Phase I trials, vaccine studies, and trials on research on preventive care for children or adults.
It is important to note that inclusion and exclusion criteria are not used to reject people personally. Instead, the criteria are used to identify appropriate participants and keep them safe. The criteria help ensure that researchers will be able to answer the questions they plan to study.

If you plan to participate, some questions you might ask about the research include:

- Why is this research being done and who is sponsoring it?
- How do the possible risks and benefits of the study compare with approved treatments for me?
- What are the possible immediate and long-term side effects?
- What other treatment options do I have?
- Will I have to pay anything to participate in the study?

Source: National Institutes of Health

WEBSITES

General Information

https://www.ciscrp.org/

Center for Information & Study on Clinical Research Participation (CISCRP)
56 Commercial Wharf East
Boston, MA 02110
Phone: 617-725-2750
CISCRP provides information on clinical trials designed to help people become informed participants. CISCRP is an independent non-profit organization dedicated to educating and informing the public and patients about clinical research. CISCRP also provides information and resources to help research and health professionals better serve their patients and study volunteers.

http://www.ChristopherReeve.org
https://www.christopherreeve.org/research/nactn/what-are-clinical-trials

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 at https://victoryoverparalysis.org/participate-in-research.

http://www.curelauncher.com/

Cure Launcher
40701 Woodward Ave, Suite 102
Bloomfield Hills, MI 48304
Phone: 248-952-8731
Email: info@curelauncher.com
Cure Launcher matches and suggests clinical trials for people at no cost to the user. They will summarize the options they found for the user. They are a patient-advocate service that pre-screens patients based on the criteria listed on clinicaltrials.gov.
Food and Drug Administration: Clinical Trials and Drug Development

Froedtert & Medical College of Wisconsin: Clinical Trial Basics
Phone: 914-805-3000

ICORD: Clinical Trials Information


MedlinePlus: Clinical Trials

NIH Clinical Research Trials and You
An NIH-hosted website for patients thinking about participating in a clinical trial.

NIH Clinical Center: FAQs About Clinical Studies

NIH Senior Health: Participating in Clinical Trials

National Institute on Aging: Clinical Trials and Older People

National Library of Medicine FAQ on Clinical Trial Results

National Library of Medicine FAQ on ClinicalTrials.gov Questions
The FAQ includes information on using ClinicalTrials.gov as well as general information on clinical trials.

WebMD: Clinical Trials: A Guide for Patients

Databases of Clinical Trials

http://www.centerwatch.com
CenterWatch
10 Winthrop Square, Fifth Floor
Boston, MA 02110
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.

http://www.ClinicalTrials.gov
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.

http://www.isrctn.com
ISRCTN Registry
ISRCTN Registry, Floor 6
236 Grays Inn Road
London, WC IX8HB
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.

http://www.searchclinicaltrials.org/
Search Clinical Trials
This database run by the Center for Information & Study on Clinical Research Participation allows people to search multiple websites for clinical trials, clinical study results and medical news.

http://www.uab.edu/medicine/sci/research
Spinal Cord Injury Information Network: Research Studies
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.

http://u2fp.org/educate/clinical-trials/
Unite 2 Fight Paralysis: Spinal Cord Injury Clinical Trials

http://apps.who.int/trialsearch
World Health Organization: International Clinical Trials Registry
The World Health Organization’s searchable database of clinical trials registered in various countries

Research Centers and Programs

http://www.research.va.gov/programs/csp/

Department of Veterans Affairs (VA): Cooperative Studies Program
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.

http://www.campaignforcure.org/

International Campaign for Cures of Spinal Cord Injury Paralysis (ICCP)
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.

http://www.spinalcordrecovery.org/

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

http://www.themiamiproject.org/studies

The Miami Project to Cure Paralysis
1095 NW 14th Terrace
Lois Pope Life Center
Miami, FL 33136
Miami, FL 33101-6960
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.

http://www.reeve.uci.edu/

**The Reeve-Irvine Research Center**
College of Medicine, University of California, Irvine
2109 Gillespie Neuroscience Research Facility
Irvine, CA 92697-4292
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**
2020 Peachtree Road NW
Atlanta, GA 30309-1465
Phone: 404-352-2020

Patient enrollment in a Phase 1/2a clinical trial is now open at Shepherd Center to study an investigational product called AST-OPC1 (oligodendrocyte progenitor cells) in newly injured patients with sensory and motor-complete cervical spinal cord injury (SCI). (dated March 2015)

**Specific Trials:**

www.SCiStar-study.com

**SCiStar Study Now Enrolling Patients with Recent Spinal Cord Injuries**
A clinical research study, called the SCiStar study, is now enrolling patients, ages 18-65, recently injured with complete cervical spinal cord injury at the neck that resulted in tetraplegia, the partial or total paralysis of arms, legs and torso. The study will evaluate the safety and activity of AST-OPC1 injections. AST-OPC1 is an investigational agent consisting of nerve cells known as oligodendrocyte progenitor cells. The study will evaluate the safety of three increasing doses of AST-OPC1 administered once between 14 and 30 days after injury. Researchers also will assess the impact on patient hand and arm function. The SCiStar study is sponsored by Asterias Biotherapeutics, a leading biotechnology company in the emerging field of regenerative medicine. Asterias Biotherapeutics will be working with well-known research and rehabilitation centers of excellence to conduct the clinical study. For more information about the SCiStar study, please visit www.SCiStar-study.com or contact Asterias Biotherapeutics at 650-433-2979 or info@SCiStarstudy.com.
The following books and videos are available for free loan from the PRC library. For more information, please visit the online catalog at: http://www1.youseemore.com/ReevePRC/default.asp

Books


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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