

A Study of Encapsulated Cell Technology (ECT) Implant for Patients With Late Stage Retinitis Pigmentosa

This study is currently recruiting patients.

Verified by Neurotech Pharmaceuticals March 2007

Sponsored by: Neurotech Pharmaceuticals

Information provided by: Neurotech Pharmaceuticals

ClinicalTrials.gov Identifier: NCT00447993

Purpose

The purpose of this study is to look at the safety and effectiveness of CNTF implants on vision in persons with retinitis pigmentosa, Usher type II & III, and Choroideremia. This research is being done because there are no effective therapies for people with these retinal degenerations. They are genetic disorders that affect our ability to see at night, and later cause tunnel vision and loss of central vision. Retinal degenerations affect the retina, a light sensitive layer of cells in the back of the eye. Slowly over time, these cells die and cause permanent loss of vision.

The implant is a small capsule that contains human retinal pigment epithelium cells. These cells have been given the ability to make CNTF and release it through the capsule membrane into the surrounding fluid. This study will look at the effect of the implant on vision loss by retinitis pigmentosa, Usher type II & III, and Choroideremia. In this study, two different CNTF dose levels will be used: a high dose and a low dose in one eye, as well as a sham (or placebo) surgery in the other eye.

Condition	Intervention	Phase
Retinitis Pigmentosa	Drug: NT-501	Phase II Phase III

[MedlinePlus](#) related topics: [Eye Diseases](#); [Genetic Disorders](#); [Retinal Disorders](#)
[Genetics Home Reference](#) related topics: [Eye Diseases](#); [Retinal Disorders](#)

Study Type: Interventional

Study Design: Treatment, Randomized, Double-Blind, Dose Comparison, Parallel Assignment, Safety/Efficacy Study

Official Title: A Phase II/III Study of Encapsulated Human NTC-201 Cell Implants Releasing Ciliary Neurotrophic Factor (CNTF) for Participants With Retinitis Pigmentosa Using Visual Acuity as the Primary Outcome

Further study details as provided by Neurotech Pharmaceuticals:

Primary Outcomes: The primary outcome is the change in best-corrected visual acuity (BCVA) using the Electronic Visual Acuity (EVA) technology at month 12.

Secondary Outcomes: Longer-term observations of change in visual acuity, disease modification, BCVA, ERG, optical coherence tomography, inflammation, and vision-related

quality of life(NEI-VFQ25).
Expected Total Enrollment: 60

Study start: January 2007

This study will involve about 16 visits over 1½ years for specific tests of the participant's vision and health. These visits may include visual exams, blood draw for laboratory testing, brief medical history and exam, and occasionally a questionnaire (survey), in addition to the visit for the surgical procedures. The primary effectiveness outcome for this study will be a visual acuity score one year after the implant surgery. There will be about 13 centers participating in this study, and up to 60 people enrolled across the US. Each participant joining the study who has completed initial screening will then be scheduled to have a brief surgical procedure performed on each eye, one of which will include a very small cell-filled implant. Follow-up visits for repeat assessments will be required regularly to determine if the implant being tested is safe and effective for use to treat RP.

Eligibility

Ages Eligible for Study: 18 Years - 64 Years, Genders Eligible for Study: Both
Criteria

Inclusion Criteria:

Criteria for patients to qualify for the study include, but are not limited to:

- Over 18 years of age, and less than 65 years of age
- Diagnosis of retinitis pigmentosa, Usher Syndrome Type 2 or 3 or Choroideremia
- Visual acuity no better than 20/80 and no worse than 20/320
- Reduced electrical responses from the retina (ERG) and loss of peripheral vision

Exclusion Criteria:

The following criteria will exclude patients from the study:

- Pregnant or lactating females, or females planning to become pregnant during the study or not using an acceptable method of contraception.
- Retinitis pigmentosa caused by a classic syndrome, including Usher Type I
- Other eye diseases including advanced cataract.
- Chronic systemic disease requiring continuous treatment with systemic steroids, immunosuppressive medications or insulin.

Location and Contact Information

Please refer to this study by ClinicalTrials.gov identifier NCT00447993
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More Information

Study ID Numbers: CNTF 3

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Health Authority: United States: Food and Drug Administration

ClinicalTrials.gov processed this record on April 16, 2007

Study Phase

Most clinical trials are designated as phase I, II, or III, based on the type of questions that study is seeking to answer:

- In Phase I clinical trials, researchers test a new drug or treatment in a small group of people (20-80) for the first time to evaluate its safety, determine a safe dosage range, and identify side effects.
- In Phase II clinical trials, the study drug or treatment is given to a larger group of people (100-300) to see if it is effective and to further evaluate its safety.
- In Phase III studies, the study drug or treatment is given to large groups of people (1,000-3,000) to confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow the drug or treatment to be used safely.
- In Phase IV studies, the post marketing studies delineate additional information including the drug's risks, benefits, and optimal use.

These phases are defined by the Food and Drug Administration in the Code of Federal Regulations.

Click the check box to the left of each study phase that you wish to include in your search. Select one or more study phases. If you do not select a specific phase, trials in any phase that match your other search terms will be retrieved.