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Study of the Safety and Efficacy of NC-503 in Secondary (AA) Amyloidosis

This study has been completed.

Sponsors and Collaborators:	Neurochem Inc. FDA Office of Orphan Products Development
Information provided by:	Neurochem Inc.
ClinicalTrials.gov Identifier:	NCT00035334

▶ Purpose

The main objective of this study is to evaluate the safety and efficacy of NC-503 compared to placebo in patients with secondary (AA) amyloidosis using a composite assessment of clinical improvement/worsening of both renal and gastrointestinal functions.

Condition	Intervention	Phase
Secondary (AA) Amyloidosis Rheumatoid Arthritis Nephrotic Syndrome Familial Mediterranean Syndrome Kidney Diseases Gastrointestinal Diseases	Drug: NC-503 (Anti-amyloidotic (AA) Agent)	Phase II Phase III

[Genetics Home Reference](#) related topics: [Digestive Diseases](#) [Kidney Diseases](#)

[MedlinePlus](#) related topics: [Digestive Diseases](#) [Kidney Diseases](#) [Metabolic Disorders](#) [Rheumatoid Arthritis](#)

[ChemIDplus](#) related topics: [Brucellosis](#)

[U.S. FDA Resources](#)

Study Type: Interventional

Study Design: Treatment, Randomized, Double-Blind, Placebo Control, Parallel Assignment, Safety/Efficacy Study

Official Title: A Phase II/III Study of the Safety and Efficacy of NC-503 in Patients Suffering From Secondary (AA) Amyloidosis

Further study details as provided by Neurochem Inc.:

Estimated Enrollment: 150
Study Start Date: October 2001
Estimated Study Completion Date: December 2004

Detailed Description:

AA amyloidosis is associated with chronic inflammatory conditions (rheumatoid arthritis, ankylosing spondylitis, inflammatory bowel disease), chronic infection (tuberculosis, osteomyelitis), and Familial Mediterranean Fever. Rheumatoid arthritis is the major cause of AA amyloidosis in Western Europe and North America. The most common clinical feature of AA amyloidosis is renal dysfunction manifested as nephrotic-range proteinuria or renal insufficiency at the time of diagnosis. End-stage renal failure is the cause of death in 40-60% of cases. Gastrointestinal involvement is also frequent and is usually manifested as chronic diarrhea, body weight loss and malabsorption. Enlargement of the liver and spleen may also occur in some patients. The median survival time from diagnosis varies from 2 to 8 years depending on the stage of the disease at time of diagnosis. The goal of the current therapy in AA amyloidosis is the control of the associated disease. However, the current approaches for the treatment of AA amyloidosis are unspecific, toxic, invasive, and not sufficiently effective in many cases. NC-503 was specifically designed to compete with the naturally occurring sulfated GAGs for the binding to amyloidogenic precursor proteins, and to inhibit amyloid deposition into tissues. The proposed therapy with NC-503 is based on the prevention of the amyloid fibril formation. The objective of this clinical phase II/III study is to determine the efficacy and safety of NC-503 compared to a placebo in patients suffering from secondary (AA) amyloidosis by the assessment of clinical improvement/ worsening of both renal and gastrointestinal functions.

Eligibility

Ages Eligible for Study: 18 Years and older
Genders Eligible for Study: Both

Criteria

PROTOCOL INCLUSION CRITERIA

- Patients must be 18 years of age or older.
- Males and females. If women of childbearing potential (i.e., not surgically sterilized or post-menopausal greater than one year) the patient must be using effective birth control.
- Diagnosis of AA amyloidosis demonstrated by positive biopsy (Congo red staining) and immunohistochemistry or immunoelectron microscopy at screening visit. Tissue from previous biopsy can be used for confirmation of diagnosis, if available.
- Persistent proteinuria defined as urinary protein excretion \geq 1g/24h in two distinct 24-h urine collections at least 1 week apart within 3 months prior to study entry (baseline, Month 0 visit) without evidence of urinary tract infection or overt heart failure (NYHA class III or more); OR creatinine clearance \geq 60 mL/min in two distinct measures at least 1 week apart within 3 months prior to study entry (baseline, Month 0 visit).
- Creatinine clearance \geq 20 mL/min AND serum creatinine \leq 3 mg/dl within 3 months prior to study entry (baseline, Month 0 visit).
- Written informed consent.

PROTOCOL EXCLUSION CRITERIA

- Evidence or suspicion of renal or renovascular diseases other than renal AA amyloidosis.
- Presence of diabetes mellitus (Type I and II).
- Evidence of a cause of potentially reversible reduced renal function, such as accelerated hypertension or drug nephrotoxicity.
- AST, ALT, or ALP $>$ 5 times the upper limit of normal, or total bilirubin 50% above upper limits of normal.
- Presence of any other clinically significant diseases that could interfere with the interpretation of study results or compromise patient safety or any conditions that could reduce life expectancy to less than two years.
- Use of an investigational drug within thirty days prior to the screening visit.
- Active alcohol and/or drug abuse.
- Initiation of or any changes in ACE inhibitor therapy within 3 months prior to the screening visit.
- Initiation of or any changes in cytotoxic agents/colchicine therapy within 3 months prior to the screening visit.
- Inability to provide legal consent.

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT00035334

 [Hide Study Locations](#)**Locations****United States, Indiana**

Indiana University School of Medicine, Department of Pathology and Laboratory Medicine,
Indianapolis, Indiana, United States, 46202

United States, Massachusetts

Boston Medical Center, Renal Division
Boston, Massachusetts, United States, 02118

United States, Minnesota

Mayo Clinic
Rochester, Minnesota, United States, 55905

United States, New York

Mount Sinai Medical Center
New York, New York, United States, 10029

Finland

Rheumatism Foundation Hospital
Heinola, Finland, FIN-18120

France

Hôpital Claude Huriez, Service de médecine Interne, Clinique Médicale A
Lille, France, CEDEX 59037
Centre Hospitalier du Mans, Service de Rhumatologie
Le Mans, France, CEDEX 1
Hôpital Cochin, Centre de Recherche et d'Explorations Fonctionnelles
Paris, France, 75679 CEDEX 14

Israel

Bnai Zion Medical Center
Haifa, Israel, 31048
Heller Institute of Medical Research, Sheba Medical Center

Tel Hashomer, Israel, 52621

Italy

Italian Group for Systemic Amyloidosis, Biotechnology Research Laboratories, IRCCS Policlinico San Matteo, Internal Medicine and Medical Oncology
Pavia, Italy, 27100

Lithuania

Vilnius University Hospital
Vilnius, Lithuania, 2001

Netherlands

University Hospital Groningen, Department of Medicine, Division of Rheumatology
Groningen, Netherlands, 9700 RB

Poland

Instytut Reumatologiczny
Warszawa, Poland, 02-632
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Russian Federation

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Moscow, Russian Federation, 115522

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Ciudad Sanitària y Universitària de Bellvitge, Servicio de Reumatologia, Hospitalet de Llobregat
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Badalona, Spain, 08916
Hospital Clinic I Provincial de Barcelona, Jefe del Departamento de Reumatologia
Barcelona, Spain, 08036
Hospital Clinico San Carlos de Madrid, Servicio de Reumatologia
Madrid, Spain, 28040

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Cerrehpasa Tip Fakultesi

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Sponsors and Collaborators

Neurochem Inc.

[FDA Office of Orphan Products Development](#)

 **More Information**

Publications:

Safety, Tolerability and Pharmacokinetic Profile of Fibrillex™ (Anti-AA Amyloid Agent) in Healthy and Renal Impaired Subjects. Garceau D., Gurbindo C., Laurin J. Neurochem Inc. Reference: Proceedings from the IXth International Symposium on Amyloidosis , 2001 (Budapest, Hungary)

Publications indexed to this study:

[Dember LM, Hawkins PN, Hazenberg BP, Gorevic PD, Merlini G, Butrimiene I, Livneh A, Lesnyak O, Puechal X, Lachmann HJ, Obici L, Balshaw R, Garceau D, Hauck W, Skinner M; Eprodisate for AA Amyloidosis Trial Group. Eprodisate for the treatment of renal disease in AA amyloidosis. N Engl J Med. 2007 Jun 7;356\(23\):2349-60.](#)

Study ID Numbers: CL-503004
First Received: May 2, 2002
Last Updated: February 13, 2006
ClinicalTrials.gov Identifier: [NCT00035334](#)
Health Authority: United States: Food and Drug Administration

Keywords provided by Neurochem Inc.:

Familial Mediterranean Fever
Amyloidosis
Secondary (AA) Amyloidosis
Nephrotic Syndrome

Study placed in the following topic categories:

Pregnancy Complications	Nephrosis
Autoimmune Diseases	Amyloidosis
Metabolic Diseases	Pathologic Processes
Gastrointestinal Diseases	Urologic Diseases
Joint Diseases	Arthritis
Arthritis, Rheumatoid	Connective Tissue Diseases
Rheumatic Diseases	Neoplasm Metastasis
Fever	Kidney Diseases
Familial Mediterranean fever	Metabolic disorder
Signs and Symptoms	Brucellosis

Additional relevant MeSH terms:

Skin and Connective Tissue Diseases	Female Urogenital Diseases
Neoplasms	Immune System Diseases
Neoplastic Processes	Musculoskeletal Diseases
Female Urogenital Diseases and Pregnancy Complications	Nutritional and Metabolic Diseases
Male Urogenital Diseases	Pathological Conditions, Signs and Symptoms
Digestive System Diseases	

ClinicalTrials.gov processed this record on January 09, 2008

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