

Randomised, Double-Blind, Placebo Controlled, Cross Over Trial of a Parenteral Modified Cobratoxin in Adrenomyeloneuropathy

Submission date 04/01/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 10/03/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 17/11/2010	Condition category Nervous System Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

AMN002

Study information

Scientific Title

Acronym

MCTX in Adrenomyeloneuropathy

Study objectives

Not provided at time of registration.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration.

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

Health condition(s) or problem(s) studied

Adrenomyeloneuropathy (AMN)

Interventions

Modified cobratoxin (0.25 mg) administered subcutaneously (sc) twice daily for 6 months versus placebo injections.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Not provided at time of registration.

Secondary outcome measures

Not provided at time of registration.

Overall study start date

10/03/2000

Completion date

10/03/2003

Eligibility

Key inclusion criteria

1. Male or female age ≥ 18 years
2. Diagnosis of AMN either biochemically or genetically
3. Have some motor disability that affects their gait
4. Willing and able to provide written informed consent
5. Willing and able to comply with study procedures

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Not provided at time of registration.

Key exclusion criteria

Not provided at time of registration.

Date of first enrolment

10/03/2000

Date of final enrolment

10/03/2003

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
National Hospital for Neurology and Neurosurgery
London
United Kingdom
WC1N 3BG

Sponsor information

Organisation
ReceptoPharm Inc. (USA)

Sponsor details
1537 NW 65th Ave
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Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
ReceptoPharm Inc.

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	26/08/2003		Yes	No