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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

Registration date
10/03/2005

Overall study status
Completed

Last Edited
17/11/2010

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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