

Amiloride Clinical Trial in Optic Neuritis

Submission date 03/05/2013	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 03/05/2013	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 06/01/2017	Condition category Eye Diseases	<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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Additional identifiers

EudraCT/CTIS number

2012-004980-39

IRAS number

ClinicalTrials.gov number

NCT01802489

Secondary identifying numbers

Study information

Scientific Title

Amiloride Clinical Trial in Optic Neuritis

Acronym

ACTION

Study objectives

The aim of this study is to investigate the neuroprotective efficacy of amiloride in the treatment of multiple sclerosis (MS).

Ethics approval required

Old ethics approval format

Ethics approval(s)

21/01/2013, ref: 13/SC/0022

Study design

Randomised interventional treatment trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Topic: Eye, Neurological; Subtopic: Eye (all Subtopics), Neurological (all Subtopics); Disease: Ophthalmology, Nervous system disorders

Interventions

Amiloride, 10mg per day active group with a double blind randomised placebo group.
Study Entry : Single Randomisation only

Intervention Type

Drug

Phase

Phase II

Drug/device/biological/vaccine name(s)

Amiloride

Primary outcome measure

Scanning Laser Polarimetry determined retinal fibre layer thickness measured at baseline, 6 and 12 months.

Secondary outcome measures

1. Colour Vision measured at baseline, and 6 months
2. Non-conventional surrogate marker of white matter and grey matter injury and connectivity by 3T MRI measured at baseline, 6 and 12 months
3. Optical Coherence Tomography - determined difference in retinal nerve fibre layer thickness measured at baseline, 6 and 12 months
4. Quality of Life Questionnaires measured at baseline, 6 and 12 months
5. Visual Electrophysiology measured at baseline and 6 months
6. Visual Function measured at baseline, 6 and 12 months

Overall study start date

19/03/2013

Completion date

31/03/2015

Eligibility**Key inclusion criteria**

1. Patients with a first episode of unilateral ON
2. Participants with an existing diagnosis of relapsing remitting MS and new onset of ON are eligible if they have not had a previous episode of ON
3. A duration of disease of ≤ 10 years
4. An EDSS (Expanded Disability Status Scale) of ≤ 3
5. No immune modulating treatment other than β -Interferon or Glatiramer Acetate at time of recruitment
6. Able to be randomised within 28 days of onset of visual symptoms
7. Visual acuity of $\leq 6/9$
8. Participant is willing and able to give informed consent for participation in the study and able to comply with study visits
9. Male or Female, aged between 18-55 years.
10. Stable dose of current regular medication for at least 4 weeks prior to study entry
11. Female participants of child bearing potential must be willing to use two effective methods of contraception (barrier methods, hormonal methods or abstinence) during the initial 5 month treatment period of the study and for one month thereafter.
12. Participant has clinically acceptable urea and electrolytes and estimated glomerular filtration rate (eGFR) >60
13. Able and willing to comply with all study requirements.
14. Willing to allow his or her General Practitioner to be notified of participation in the study.

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

UK Sample Size: 46; Description: 23 in the active group and 23 in the placebo comparator group

Key exclusion criteria

1. Previous diagnosis of ON
2. Any concomitant immune suppressing or immune modulating therapy excluding β -interferon or glatiramer acetate.
3. Female participants who are pregnant, lactating or planning pregnancy during the course of the study.
4. Concomitant potassium supplements, angiotensin converting enzyme inhibitors, angiotensin II antagonists, cyclosporine, tacrolimus or lithium
5. Any contra-indication to MRI severe claustrophobia, metal implant, pacemaker, etc.
6. Participant who is terminally ill or is inappropriate for placebo medication
7. Impaired renal function : eGFR ≤ 60 , anuria, acute or chronic renal insufficiency and evidence of diabetic nephropathy
8. Raised serum potassium (K^+ >5.5 mmol/l)
9. Diabetes
10. Significant concomitant eye disease in either eye that may affect diseased or fellow eye results.
11. Any other significant disease or disorder which, in the opinion of the investigator, may either put the participants at risk because of participation in the study, or may influence the result of the study, or the participants ability to participate in the study.
12. Participants who have participated in another research study involving an investigational product in the past 12 weeks.

Date of first enrolment

19/03/2013

Date of final enrolment

31/03/2015

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

Dept of Clinical Neurology
Oxford
United Kingdom
OX3 9DU

Sponsor information

Organisation

University of Oxford (UK)

Sponsor details

University Offices
Wellington Square
Oxford
England
United Kingdom
OX1 2JD

Sponsor type

University/education

Website

<http://www.ox.ac.uk/>

ROR

<https://ror.org/052gg0110>

Funder(s)

Funder type

Charity

Funder Name

Multiple Sclerosis Society (of Great Britain & Northern Ireland); Grant Codes: 952/11

Alternative Name(s)

Multiple Sclerosis Society of Great Britain and Northern Ireland, The MS Society, MS Society UK, Multiple Sclerosis Society UK, MS Society

Funding Body Type

Private sector organisation

Funding Body Subtype

Associations and societies (private and public)

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Planned publication in a peer reviewed journal.

Intention to publish date

31/12/2015

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	09/11/2015		Yes	No
HRA research summary			28/06/2023	No	No