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Amiloride Clinical Trial in Optic Neuritis

Submission date 03/05/2013	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 03/05/2013	**Overall study status** Completed	
Last Edited 06/01/2017	**Condition category** Eye Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Matthew Craner

Contact details
Dept of Clinical Neurology
Level 6
West wing
Headley Way
Headington
Oxford
United Kingdom
OX3 9DU
+44 1865 222351
matthew.craner@ndcn.ox.ac.uk

Additional identifiers

ClinicalTrials.gov (NCT)
NCT01802489

Clinical Trials Information System (CTIS)
2012-004980-39

Protocol serial number
13895

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

Study type(s)
Treatment

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

Key secondary outcome(s))

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 Fuction measured at baselne, 6 and 12 months

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 ≤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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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+ >5.5mmol/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
United Kingdom

England

Study participating centre
Dept of Clinical Neurology
Oxford
United Kingdom
OX3 9DU

Sponsor information

Organisation
University of Oxford (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)
mssocietyuk, MS Society UK, Multiple Sclerosis Society UK, Multiple Sclerosis Society of Great Britain and Northern Ireland, The MS Society, MS Society

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United Kingdom

Results and Publications

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