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Efficacy, tolerability and safety of 0.2% Brimonidine-Tartrate for the treatment of acute non-arteritic anterior ischaemic optic neuropathy

Submission date
12/09/2003

Recruitment status
No longer recruiting

Registration date
12/09/2003

Overall study status
Completed

Last Edited
04/04/2016

Condition category
Eye Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof I Gottlob

Contact details
University Hospitals of Leicester
c/o Research and Development Office
Leicester General Hospital NHS Trust
Leicester
United Kingdom
LE1 4PW
+44 (0)116 258 4109
nicola.turner@uhl-tr.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0123109164

Study information

Scientific Title
Efficacy, tolerability and safety of 0.2% Brimonidine-Tartrate for the treatment of acute non-arteritic anterior ischaemic optic neuropathy (NAION): a 3-month, double-masked, randomised and placebo-controlled trial

Study objectives
To investigate the effect of this medication which is free from harmful side effects in NAION.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Double-masked randomised and placebo-controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Eye Diseases: Non-arteritic anterior ischemic optic neuropathy

Interventions
Randomised controlled trial

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Brimonidine-Tartrate

Primary outcome measure
Safety of 0.2% Brimonidine-Tartrate for the treatment of acute non-arteritic anterior ischemic optic neuropathy (NAION)

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/07/2001

Completion date
30/06/2003

Eligibility

Key inclusion criteria
Patients with acute non-arteritic anterior ischemic optic neuropathy

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
Not provided at time of registration

Key exclusion criteria
Does not match inclusion criteria

Date of first enrolment
01/07/2001

Date of final enrolment
30/06/2003

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University Hospitals of Leicester
Leicester
United Kingdom
LE1 4PW

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Hospitals of Leicester NHS Trust (UK)

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