ISRCTN59484478 https://doi.org/10.1186/ISRCTN59484478

Assessment of Detection of Apoptosing Retinal Cells in glaucoma

Submission date 22/09/2006	**Recruitment status** Stopped	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 24/10/2006	**Overall study status** Stopped	
Last Edited 03/08/2015	**Condition category** Eye Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr M Francesca Cordeiro

Contact details
Institute of Ophthalmology,
UCL,
11-43 Bath Street
London
United Kingdom
EC1V 9EL

Additional identifiers

EudraCT/CTIS number
2006-005273-22

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
DARC1

Study information

Scientific Title
Assessment of Detection of Apoptosing Retinal Cells in glaucoma

Acronym
DARC in glaucoma

Study objectives
Detection of Apoptosing Retinal Cells (DARC) is a new imaging technique that may be used to identify and monitor early retinal neurodegeneration in glaucoma.

Updated 03/08/2015:
This trial did not go ahead in the format described in ISRCTN59484478. Following the review of the IMP pre-clinical data by the MHRA scientific advisory group, the design of the trial needed to change significantly. These significant changes in design made this a new trial. It was decided that the new trial would be registered with the trial sponsors' account on another registered public clinical trial database.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local and national ethics application currently under review

Study design
3 stages:
1. Cross-sectional pilot study to evaluate DARC counts
2. Prospective investigator masked randomised active placebo-controlled pilot
3. Longitudinal pilot study to correlate DARC counts

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Screening

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
Glaucoma

Interventions

In the treatment part of the study looking at the effect of brimonidine on glaucoma in patients with progressing disease, patients will be randomised to treatment with brimonidine or placebo. This group of patients will already be on at least first-line anti-glaucoma Intra-Ocular Pressure (IOP) lowering treatment so that addition of brimonidine as an additional treatment would be normal clinical practice. The placebo group of progressing patients will obviously not be getting this additional treatment, but this group is important to include if we are to accurately assess brimonidine efficacy. All patients in the treatment arm of the study will be regularly assessed for IOP control hence any patient shown to have inadequate control of IOP will be withdrawn from the study, so that appropriate treatment can be instigated. In other words, any patient on placebo with inadequate IOP control will be withdrawn from the study.

Eligible subjects in the treatment groups (i.e., progressing and non progressing) will be randomised in a 1:1 ratio to receive either a fixed or non-fixed formulation containing brimonidine twice a day or placebo twice a day. IOP will be checked at baseline, and after 4 weeks, 3, 6, 12 and 18 months of treatment. Dosing will be at 9 am and 9 pm. All patients will already be on treatment (except brimonidine) for IOP.

All study medication will be supplied in identical SSP oval bottles filled to a volume of 5 ml with either Alphagan/Combigan or placebo. Bottles will be supplied in individual boxes by Allergan Pharmaceuticals. Subjects will be instructed to store opened bottles of study medication in the boxes. To minimise potential bias towards the outcome of the study by subjects, investigators and study personnel regarding the safety, efficacy and comfort of the test articles, the study will be investigator masked. Subjects will be randomised to receive either Alphagan/Combigan or Placebo in a 1:1 ratio. The investigator or study staff will enrol qualified subjects into the study in a sequential manner by subject number, beginning with the first number in a numerical series assigned by the CRO. The randomisation list will be kept in the pharmacy and the subject will collect medication, labelled A or B or C, from the pharmacy and be dispensed the medication according to the study number from the randomisation list.

There are three stages:

Stage 1: a cross-sectional pilot study to evaluate DARC counts in age-matched groups of 'normals' to non-progressing and progressing glaucoma patients, and ocular hypertensive and normal tension glaucoma patients.

Stage 2: a prospective investigator masked randomised active placebo-controlled pilot study comparing age-matched groups of 'normals' to non-progressing and progressing glaucoma patients to establish baseline DARC counts before and after treatment with brimonidine or brimonidine-containing formulation.

Stage 3: a longitudinal pilot study to correlate DARC counts to visual field assessment and analysis of optic disc cupping in age-matched groups of 'normals' and ocular hypertensive and normal tension glaucoma patients.

Intervention Type

Drug

Phase

Not Applicable

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

Primary outcome measure
The primary outcome measure is the DARC count

Secondary outcome measures
The secondary measures are the visual field and optic disc assessment

Overall study start date
01/12/2006

Completion date
31/08/2011

Eligibility

Key inclusion criteria
Our patient group will be identified from the glaucoma clinics at The Western Eye Hospital according to the following inclusion criteria:
1. For all patient groups:
1.1. Aged 18 years or over
1.2. Clear optical media in the studied eye
1.3. Previous experience at automated perimetry
1.4. No ocular or systemic disease (other than glaucoma in the test group)
1.5. Refractive error not higher than spherical equivalent of 6 D
1.6. Best corrected visual acuity equal to 6/9 or better
2. All subjects will have to have been shown to be able to perform reliable visual field testing using the HFA 640 instrument, central 24-2 program, to yield full thresholds (Deviation, MD-HFA and Pattern Standard Deviation, PSD-HFA), and have had good fundoscopy with assessment of their optic disc
3. Subjects willing and able to make the required study visits
4. All subjects must be able to understand the information describing the study and give informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
98

Key exclusion criteria
1. History of current or severe, unstable or uncontrolled cardiovascular, hepatic or renal disease (e.g., sinus bradycardia, cardiac failure) precluding safe administration of a topical beta antagonists
2. History of bronchial asthma or chronic obstructive airways disease precluding use of a topical beta antagonist
3. Women of childbearing age will be excluded from the study unless they have been surgically sterilised
4. Contact lens wearers will not be allowed to participate in the study
5. Previous ocular surgery such as retinal detachment, multiple surgical procedures including glaucoma
6. Co-existing disease which may affect DARC count e.g., retinal vein occlusion, age-related macular degeneration (AMD)

Date of first enrolment
01/12/2006

Date of final enrolment
31/08/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Institute of Ophthalmology,
London
United Kingdom
EC1V 9EL

Sponsor information

Organisation
St Mary's Hospital NHS Trust (UK)

Sponsor details
The Western Eye Hospital
Marylebone Road
London
England
United Kingdom
NW1 5YE

Sponsor type
Hospital/treatment centre

Website
http://www.st-marys.nhs.uk/index.html

ROR
https://ror.org/01aysdw42

Funder(s)

Funder type
Charity

Funder Name
Unrestricted educational grant

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