Viscogonioplasty in narrow angle glaucoma

Submission date [] Prospectively registered Recruitment status 08/02/2010 No longer recruiting [] Protocol [] Statistical analysis plan Registration date Overall study status 14/04/2010 Completed [X] Results [] Individual participant data Last Edited Condition category 15/07/2013 **Eye Diseases**

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

SLREC: 05/Q0904/111

Study information

Scientific Title

Evaluation of efficacy and safety of viscogonioplasty in narrow angle glaucoma: a randomised single blind single centre controlled trial

Study objectives

Viscogonioplasty combined with cataract surgery in patients with narrow angle glaucoma will have a greater effect on intraocular pressure than cataract surgery alone.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Sunderland local research ethics committee (LREC) approved on the 21st February 2006 (ref: 05/Q0904/111)

Study design

Randomised single centre single-blind controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

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

Narrow angle glaucoma

Interventions

Cataract surgery combined with viscogonioplasty or cataract surgery alone. Follow-up of the patients intraocular pressure was for 12 months post-operation with a clinic visit at 3, 6 and 12 months.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Intraocular pressure lowering following cataract surgery and viscogonioplasty versus catarct surgery alone, measured at 12 months

Secondary outcome measures

- 1. Opening of drainage angle when examined on gonioscopy, measured at 12 months
- 2. Complications following viscogonioplasty, measured immediately following surgery

Overall study start date

01/02/2006

Completion date

01/02/2007

Eligibility

Key inclusion criteria

- 1. Patients with evidence of glaucoma, presence of a narrow drainage angle defined as:
- 1.1. Less than 90 degrees of the trabecular meshwork visible on gonioscopy
- 1.2. Previous patent laser peripheral iridotomy
- 1.3. Presence of cataract
- 2. Any age, any gender

Participant type(s)

Patient

Age group

Other

Sex

Both

Target number of participants

34 patients

Key exclusion criteria

- 1. Plateau iris syndrome
- 2. Other glaucomas
- 3. Previous glaucoma surgery
- 4. History of ocular injury
- 5. Participation in any other glaucoma research

Date of first enrolment

01/02/2006

Date of final enrolment

01/02/2007

Locations

Countries of recruitment

England

United Kingdom

Study participating centre Sunderland Eye Infirmary Sunderland

Sunderland United Kingdom SR2 9HP

Sponsor information

Organisation

City Hospitals Sunderland NHS Foundation Trust (UK)

Sponsor details

Kayll Road Sunderland England United Kingdom SR2 7TP +44 (0)191 565 6256 wendy.adams@chs.northy.nhs.uk

Sponsor type

Hospital/treatment centre

Website

http://www.sunderland.nhs.uk/chs/

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Sunderland Eye Infirmary (UK) - covered incidental costs

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	08/12/2010		Yes	No