Comparison of the effect of Aqualase and Phacoemulsification Cataract Surgery on Corneal Endothelium

Submission date Recruitment status Prospectively registered 29/09/2006 No longer recruiting [] Protocol Statistical analysis plan Registration date Overall study status 29/09/2006 Completed [X] Results [] Individual participant data Last Edited Condition category 11/05/2009 **Eve Diseases**

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Mr Laurence Whitefield

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers N0533171160

Study information

Scientific Title

Study objectives

To determine any potential difference in effect on corneal endothelial cell loss between two methods for removing cataracts: aqualase and phacoemulsification.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

Health condition(s) or problem(s) studied

Eye Diseases: Cataract

Interventions

- 1. Aqualase
- 2. Phacoemulsification

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Corneal endothelial cell counts and coefficient of variation of cell size

Secondary outcome measures

Not provided at time of registration

Overall study start date

Completion date

01/10/2006

Eligibility

Key inclusion criteria

Patients who have requested removal of soft to moderately dense cataracts.

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

100

Key exclusion criteria

- 1. Ocular co-morbidity resulting in anterior segment pathology
- 2. Previous intra-ocular inflammation
- 3. Raised intra-ocular pressure
- 4. Previous intra-ocular surgery

Date of first enrolment

01/10/2005

Date of final enrolment

01/10/2006

Locations

Countries of recruitment

England

United Kingdom

Study participating centre Queen Mary's Sidcup NHS Trust

Sidcup United Kingdom DA14 6LT

Sponsor information

Organisation

Record Provided by the NHSTCT Register - 2006 Update - Department of Health

Sponsor details

The Department of Health, Richmond House, 79 Whitehall London United Kingdom SW1A 2NL +44 (0)20 7307 2622 dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type

Government

Funder Name

Queen Mary's Sidcup 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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2008		Yes	No