ISRCTN41218609 https://doi.org/10.1186/ISRCTN41218609

The effect of cataract surgical techniques on the corneal endothelium: a comparison between conventional phacoemulsification with Aqualase

Submission date 28/09/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 28/09/2007	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 29/09/2011	**Condition category** Eye Diseases	[_] 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
Mr Scott Hau

Contact details
Moorfields Eye Hospital
162 City Road
London
United Kingdom
EC1V 2PD
+44
Scott.Hau@moorfields.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0141187713

Study information

Scientific Title

Study objectives
To compare two techniques of cataract surgery: conventional phacoemulsification versus the newer Aqualase technique especially looking at the rate of corneal endothelial cell loss and complications rate seen with each technique.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled pilot study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Eye Diseases: Cataract

Interventions
1. Standard phacoemulsification
2. Aqualase

Intervention Type
Other

Phase
Not Specified

Primary outcome measure

Percentage of cell loss

Secondary outcome measures
1. Coefficient of variation and hexagonality of cell sizes at 3 months
2. Per-and-postoperative complications

Overall study start date
20/09/2006

Completion date
20/12/2006

Eligibility

Key inclusion criteria
Routine cataracts less than or equal to grade 3 determined by Oxford grading scale

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
30 patients - 30 eyes in each group

Key exclusion criteria
1. Other ocular or systemic co-morbidity factors
2. Patients with an axial length greater than 26.5mm
3. Combined procedures
4. Cataracts greater than grade 3

Date of first enrolment
20/09/2006

Date of final enrolment
20/12/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Moorfields Eye Hospital
London
United Kingdom
EC1V 2PD

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2007 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
Moorfields Eye Hospital NHS Foundation Trust (UK) NHS R&D Support Funding

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