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Evaluation of cataract surgery and lens implantation in diabetics

Submission date 30/10/2009	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 15/12/2009	**Overall study status** Completed	
Last Edited 02/10/2017	**Condition category** Eye Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
09/H0402/107

Study information

Scientific Title
Comparison of glistenings in two hydrophobic acrylic intraocular lenses after cataract surgery in diabetics: a randomised controlled trial

Study objectives
Hydrophobic acrylic intraocular lenses (IOL) account for the majority of the market in the UK. In some patients microvacuoles known as glistenings are seen to form in the IOL material in the first 2 years after surgery. These do not affect visual acuity after surgery, but could cause light scatter in the eye and glare. They are seen more commonly clinically in eyes with damaged blood aqueous barriers, such as in diabetes or uveitis.

Recently a new intraocular lens (AVS) which has a slightly higher water content (4% versus less than 1%) does not appear to develop glistenings. The aim of this study is to compare this IOL with a standard hydrophobic IOL in diabetic patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
St Thomas' Research Ethics Committee, 27/10/2009

Study design
Randomised 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 to request a patient information sheet

Health condition(s) or problem(s) studied
Cataract

Interventions
AVS hydrophobic intraocular lens versus AcrySof® intraocular lens. Patients will be randomised to have routine cataract surgery to one eye with implantation of either the Santen or the AcrySof® lens. Randomisation will be via a remote computer based website. Surgery to the second eye will be performed within 6 weeks of the first operation by the same surgeon, with the other intraocular lens type.

Patients will be followed up for a total of 3 years.

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Glistenings
2. Vision
Taken at 1, 3, 6, 12, 24 and 36 months.

Secondary outcome measures
1. Post-operative inflammation after cataract surgery and cellular deposition on the IOL surface
2. Objective optical quality and wave-front aberration
3. Contrast sensitivity
4. Diabetic retinopathy after cataract surgery
Taken at 1, 3, 6, 12, 24 and 36 months.

Overall study start date
01/01/2010

Completion date
01/01/2013

Eligibility

Key inclusion criteria
1. Bilateral cataracts requiring surgery
2. Diabetic
3. Aged 18 years or over, either sex

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40

Key exclusion criteria
Diabetic maculopathy

Date of first enrolment
01/01/2010

Date of final enrolment
01/01/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
St Thomas' Hospital
London
United Kingdom
SE1 7EH

Sponsor information

Organisation
Guys and St Thomas' Hospital NHS Foundation Trust (UK)

Sponsor details
c/o Karen Ignatian
London
England
United Kingdom
SE1 7EH

Sponsor type
Hospital/treatment centre

Website
http://www.guysandstthomas.nhs.uk/

ROR
https://ror.org/00j161312

Funder(s)

Funder type
Charity

Funder Name
Fight for Sight (UK)

Alternative Name(s)
Fight for Sight, Inc., National Council to Combat Blindness, Fight for Sight (U.S.), FFS

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United States of America

Funder Name
Advanced Vision Science (AVS) (UK) - providing intraocular lenses

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