

Evaluation of cataract surgery and lens implantation in diabetics

Submission date 30/10/2009	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 15/12/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 02/10/2017	Condition category Eye Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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(s)

1. Glistenings
2. Vision

Taken at 1, 3, 6, 12, 24 and 36 months.

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

Diabetic maculopathy

Date of first enrolment

01/01/2010

Date of final enrolment

01/01/2013

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

St Thomas' Hospital

London

United Kingdom

SE1 7EH

Sponsor information

Organisation

Guys and St Thomas' Hospital NHS Foundation Trust (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

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?
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