ISRCTN36436933 https://doi.org/10.1186/ISRCTN36436933

What is the best anti-scarring treatment for combined cataract and drainage surgery in routine operations for combined glaucoma and cataract in Tanzania?

Submission date
24/09/2009

Recruitment status
No longer recruiting

Registration date
30/11/2009

Overall study status
Completed

Last Edited
09/09/2016

Condition category
Eye Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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
N/A

Study information

Scientific Title
Is beta-radiation better than 5-fluorouracil as an adjunct for trabeculectomy when combined with cataract surgery? A single centre randomised controlled trial

Study objectives
Beta radiation offers improved pressure control with a retained safety profile when used as an adjunct in combined trabeculectomy and cataract surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Institute for Medical Research and Ministry of Health and Social Welfare, Dar es Salaam (Tanzania) provided clearance certificates for conducting Medical Research in Tanzania, 25/07/2008 and 13/08/2008, ref: NIMR/HQ/R.8a/Vol.IX/717 and NIMR/HQ/R.8a/Vol.IX/723

Study design
Single-centre randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Open angle glaucoma

Interventions
Patients are randomised to either 5-fluorouracil or beta-radiation as follows:
1. 5-fluorouracil is applied subconjunctivally for a period of 3 minutes at a concentration of 50 mg/ml prior to undertaking the drainage flap
2. Beta-radiation is applied with a Strontium-90 containing delivery device to the closed conjuntival surface at the conclusion of surgery. Using the decay chart for the probe the correct time interval is used to deliver 1000 cGy of Beta irradiation (approximately 8 minutes).
The main outcome is at one year post-operatively.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Beta-radiation, 5-fluorouracil

Primary outcome(s)

Intraocular pressure at 12 months post-operatively. Surgical success at twelve months is defined as a maximum intraocular pressure less than 16 mmHg as measured using Goldmann tonometry on no ocular hypotensive therapy.

Key secondary outcome(s))
1. Visual function, assessed within or at the first year after surgery
2. Reintervention, assessed within or at the first year after surgery
3. Reintervention acceptance, assessed within or at the first year after surgery
4. Surgical complications, measured during surgery and within two weeks of surgery

Completion date
01/05/2014

Eligibility

Key inclusion criteria
1. Consent to inclusion and participation in trial
2. Characteristic glaucomatous changes in the optic disc. The presence of a focal or diffuse area of optic disc rim loss, so that the neuroretinal rim tissue in any quadrant is less than 5% of the disc diameter in that meridian. Extensive loss of neuroretinal rim tissue with marked optic disc cupping giving a cup disc ratio greater than 0.8.
3. A measured intraocular pressure greater than or equal to 21 mmHg on at least one visit before the time of listing for surgery as measured by Goldmann applanation tonometry
4. An open angle on gonioscopy
5. Visually significant cataract
6. Aged greater than 20 years, either sex

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Unwillingness to participate in the study
2. Anterior segment neovascularisation
3. Past trauma to the eye or ocular adnexae
4. Retinal or optic nerve neovascularisation
5. Aphakia or pseudophakia
6. Previous ocular surgery
7. Uveitis
8. Inability/unwillingness to give informed consent
9. Unwillingness to accept randomisation

10. Patient less than 20 years of age
11. Pregnancy or female of childbearing age who may be pregnant at time of treatment (last menstrual period [LMP])
12. No clinically significant cataract
13. Chronic use of topical or systemic steroids

Date of first enrolment
01/05/2009

Date of final enrolment
01/05/2014

Locations

Countries of recruitment
United Kingdom

England

Tanzania

Study participating centre
Insititute of Ophthalmology
London
United Kingdom
EC1V 9EL

Sponsor information

Organisation
University College London (UCL) (UK)

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Charity

Funder Name
Fight for Sight (UK) (ref: DFFM/UCL)

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
International Glaucoma Association (UK) (ref: DEHC/UCL)

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?
Results article	results	08/09/2016		Yes	No