

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

<b>Submission date</b> 24/09/2009	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 30/11/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 09/09/2016	<b>Condition category</b> Eye Diseases	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Mr Ian Murdoch

**Contact details**  
Epidemiology and International Eye Health  
Department of Genetics  
Institute of Ophthalmology  
Bath Street  
London  
United Kingdom  
EC1V 9EL  
-  
i.murdoch@ucl.ac.uk

## Additional identifiers

EudraCT/CTIS number

IRAS number

**ClinicalTrials.gov number**

**Secondary identifying numbers**

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

### **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 below to request a patient information sheet

### **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

conjunctival 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 measure**

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.

**Secondary outcome measures**

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

**Overall study start date**

01/05/2009

**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

**Age group**

Adult

**Sex**

Both

**Target number of participants**

298

**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**

England

Tanzania

United Kingdom

**Study participating centre**

Institute of Ophthalmology

London

United Kingdom

EC1V 9EL

**Sponsor information****Organisation**

University College London (UCL) (UK)

**Sponsor details**

Epidemiology and International Eye Health  
Department of Genetics  
Institute of Ophthalmology  
Bath Street  
London  
England  
United Kingdom  
EC1V 9EL  
-  
i.murdoch@ucl.ac.uk

**Sponsor type**

University/education

**Website**

<http://www.ucl.ac.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

## 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?
<a href="#">Results article</a>	results	08/09/2016		Yes	No