

The evaluation of adjunctive beta-irradiation for trabeculectomy in South Africa: does it enhance operative success and reduce overall failure in glaucoma management?

Submission date 22/07/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 22/07/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 06/02/2015	Condition category Surgery	<input type="checkbox"/> 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

056045

Study information

Scientific Title

The evaluation of adjunctive beta-irradiation for trabeculectomy in South Africa: does it enhance operative success and reduce overall failure in glaucoma management?

Study objectives

To determine the feasibility of adjunctive beta-irradiation for trabeculectomy in an African setting. To determine the efficacy of adjunctive beta irradiation for trabeculectomy in African glaucoma in South Africa. To establish the pattern of attendance after primary trabeculectomy in an African setting and compliance with subsequent health interventions.

Ethics approval required

Old ethics approval format

Ethics approval(s)

This study was approved by the research ethics committees of all included centres, along with the Institute of Ophthalmology.

Study design

Randomised prospective double-blind controlled surgical trial of trabeculectomy with either peri-operative Beta irradiation or placebo augmentation

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Glaucoma

Interventions

African patients with established primary open angle glaucoma requiring trabeculectomy are recruited in three participating centres in South Africa. Following randomisation, patients undergo primary trabeculectomy with either exposure to 1000 cGy of Beta irradiation at the conclusion of surgery with a Strontium-90 containing delivery device, or a placebo exposure with an apparently identical device. Intraocular pressure is measured at regular intervals for at least 12 months.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Peri-operative Beta irradiation

Primary outcome(s)

Intraocular pressure at 12 months.

Key secondary outcome(s))

1. Visual assessment
2. Re-intervention rate
3. Surgical complications

Completion date

31/01/2004

Eligibility**Key inclusion criteria**

1. Consent to inclusion and participation in trial
2. Characteristic glaucomatous changes in the optic disc
3. 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
4. Extensive loss of neuroretinal rim tissue with marked optic disc cupping giving a cup disc ratio greater than 0.8
5. 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
6. An open angle on gonioscopy

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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 (LMP)
12. Clinically significant cataract
13. Chronic use of topical or systemic steroids

Date of first enrolment

03/11/1999

Date of final enrolment

19/06/2002

Locations

Countries of recruitment

United Kingdom

England

South Africa

Study participating centre

University College London

London

United Kingdom

EC1V 9EL

Sponsor information

Organisation

University College London (UK)

ROR

<https://ror.org/02jx3x895>

Funder(s)

Funder type

Charity

Funder Name

Wellcome Trust

Alternative Name(s)**Funding Body Type**

Private sector organisation

Funding Body Subtype

International organizations

Location

United Kingdom

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	04/11/2006		Yes	No