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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

Registration date
22/07/2005

Overall study status
Completed

Last Edited
06/02/2015

Condition category
Surgery

[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
Intraocular pressure at 12 months.

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

Overall study start date
03/11/1999

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

Age group
Not Specified

Sex
Not Specified

Target number of participants
320

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
England

South Africa

United Kingdom

Study participating centre
University College London
London
United Kingdom
EC1V 9EL

Sponsor information

Organisation
University College London (UK)

Sponsor details
11 - 42 Bath Street
London
England
United Kingdom
EC1V 9EL

Sponsor type
University/education

Website
http://www.ucl.ac.uk/ioo/

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

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?
Results article	results	04/11/2006		Yes	No