

The use of β radiation as an adjunct to trabeculectomy in glaucoma

Submission date 23/01/2004	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 23/01/2004	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 03/12/2008	Condition category Eye Diseases	☐ 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
LORS LT68X

Study information

Scientific Title

Study objectives

To improve the results of trabeculectomy in patients with glaucoma. About 20% of treatments fail because of the development of scar tissue over the fistula.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Not Specified

Health condition(s) or problem(s) studied

Eye diseases

Interventions

It is proposed to use 750-1000 cGY of beta radiation to the eye following surgery. Patients will be randomised to receive an active or a dummy plaque and clinically followed up with measurements of intra ocular pressure. (10P).

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Success defined as reduction in from baseline at peak drug effect, response rate and quality of life as measured using the Glaucoma disability index. IOP <21 mm Hg.

1. Completed = without medication
2. Qualified = with additional medication

Key secondary outcome(s)

Not provided at time of registration

Completion date

31/03/1996

Eligibility**Key inclusion criteria**

Patients undergoing trabeculectomy

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

Key exclusion criteria

'High-risk' glaucoma including juvenile glaucoma

Date of first enrolment

04/01/1993

Date of final enrolment

31/03/1996

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Leeds General Infirmary

Leeds

United Kingdom

LS1 3EX

Sponsor information

Organisation

NHS R&D Regional Programme Register - Department of Health (UK)

Funder(s)

Funder type

Government

Funder Name

NHS Executive Northern and Yorkshire (UK)

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	01/02/2002		Yes	No