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

Submission date 23/01/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 23/01/2004	**Overall study status** Completed	
Last Edited 03/12/2008	**Condition category** Eye Diseases	

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. I0P <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