

# The use of $\beta$ radiation as an adjunct to trabeculectomy in glaucoma

<b>Submission date</b> 23/01/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 23/01/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 03/12/2008	<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

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
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

## Secondary study design

Randomised controlled trial

## Study setting(s)

Not specified

## Study type(s)

Not Specified

## Participant information sheet

## 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 measure

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

### **Secondary outcome measures**

Not provided at time of registration

### **Overall study start date**

04/01/1993

### **Completion date**

31/03/1996

## **Eligibility**

### **Key inclusion criteria**

Patients undergoing trabeculectomy

### **Participant type(s)**

Patient

### **Age group**

Not Specified

### **Sex**

Not Specified

### **Target number of participants**

Not provided at time of registration

### **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**

England

United Kingdom

**Study participating centre**  
**Leeds General Infirmary**  
Leeds  
United Kingdom  
LS1 3EX

## **Sponsor information**

### **Organisation**

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

### **Sponsor details**

The Department of Health  
Richmond House  
79 Whitehall  
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United Kingdom  
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### **Sponsor type**

Government

### **Website**

<http://www.doh.gov.uk>

## **Funder(s)**

### **Funder type**

Government

### **Funder Name**

NHS Executive Northern and Yorkshire (UK)

## **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	01/02/2002		Yes	No