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Bleb Dysesthesia Trial

Submission date 30/09/2004	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 30/09/2004	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 29/05/2014	**Condition category** Surgery	[ ] Individual participant data [ ] Record updated in last year

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
N0203125674; N0199129912; N0176115690

Study information

Scientific Title
A randomised trial of the effect of bleb site on eye comfort following trabeculectomy

Study objectives

To investigate long-term post-operative eye discomfort following glaucoma surgery; in particular whether two different wound locations and therefore eye fluid drainage, differ in the level of eye comfort experienced as measured by a validated questionnaire, the 'Glaucoma Symptom Scale'.

On 14/07/2011 the following changes were made to this trial record:
1. The end date was changed from 31/12/2008 to 30/06/2010.
2. The target number of participants was changed from 40 to 150.
3. The trial was originally a multi-centre trial but due to recruitment issues at other centres the Oxford site proceeded single-handedly.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Oxford Research Ethics Committee B, 10/09/2002, ref: C02.200

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Surgery: Trabeculectomy

Interventions
The study design is a randomised trial designed to compare two accepted variations in surgical techniques of trabeculectomy and its effect on postoperative eye comfort. Patients who are undergoing first trabeculectomy will be approached to participate in the study. Patients will either be recruited in person or by invitation letter. When the patient gives written consent, they are randomised either to superior trabeculectomy or superonasal trabeculectomy. At the pre-operative visit they will answer a 10-question self-administered questionnaire, the Glaucoma Symptom Scale. Some pre-operative data will be collected on study forms identified only by hospital number and study number.

During the trabeculectomy, the bleb will be placed below the middle upper lid, or placed below the more inner upper lid.

After the trabeculectomy, usual medical care will take place uninfluenced by their participation in this study. At the 6-month post-operative visit, the patient will be examined for the study and a second Glaucoma Symptom Scale questionnaire will be completed by the patient. The examination will record clinical findings such as visual acuity, eye pressure and eye examination findings. The study ends here and patients continue their usual care.

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome(s)
1. Eye comfort at 6 months post-surgery as measured by the Glaucoma Symptom Scale
2. Eye features associated with eye discomfort (dysesthesia) at 6 months post-surgery

Key secondary outcome(s))
No secondary outcome measures

Completion date
30/06/2010

Eligibility

Key inclusion criteria
1. Aged 18 years and over, either sex
2. Listed for trabeculectomy
3. Satisfy the inclusion criteria

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
Does not match inclusion criteria

Date of first enrolment
10/09/2002

Date of final enrolment
30/06/2010

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
John Radcliffe Hospital
Oxford
United Kingdom
OX3 9DU

Sponsor information

Organisation
Department of Health

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Royal Devon and Exeter NHS Trust (UK)

Funder Name
Royal Berkshire and Battle Hospitals NHS Trust (UK)

Funder Name
Oxford Radcliffe Hospitals NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration