

To determine whether an eye shield is necessary following uncomplicated phacoemulsification cataract surgery

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 25/03/2020	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

N0084125075

Study information

Scientific Title

To determine whether an eye shield is necessary following uncomplicated phacoemulsification cataract surgery

Study objectives

To determine whether there are increased post-operative complications in patients using an eye shield.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Prospective randomised case controlled study

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Surgery: Cataract

Interventions

The study group will be 75 patients with uncomplicated phacoemulsification in whom an eye shield will be used in the postop period over the operated eye. The shield will be used at night for a period of 1 week. The control group will comprise 75 patients with uncomplicated phacoemulsification with no eye shield for use in the postoperative period. A similar operative technique will be employed for each patient selected for this study. As far as possible the same anaesthetic technique will be used for each patient. Patients with coexisting or previous ocular pathology other than cataract will not be included.

Following surgery patients will be randomised to one of the two groups. Information will be gathered by standardised questionnaire administered by ophthalmic nursing staff one week after surgery during their routine post operative visit.

Intervention Type

Procedure/Surgery

Phase

Not Specified

Primary outcome(s)

Outcome of surgery, patient questionnaire.

Key secondary outcome(s)

Not provided at time of registration

Completion date

01/12/2003

Eligibility

Key inclusion criteria

Adults following cataract surgery uncomplicated by operative problems. Chosen randomly at preoperative assessment.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

Key exclusion criteria

1. Intraoperative complications
2. Existing ocular pathology
3. Patients with one good seeing eye

Date of first enrolment

19/06/2003

Date of final enrolment

01/12/2003

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Hull Royal Infirmary

Hull

United Kingdom

HU3 2JZ

Sponsor information

Organisation

Department of Health

Funder(s)

Funder type

Government

Funder Name

The North and South Bank Research and Development Consortium (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration