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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 [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 30/09/2004	**Overall study status** Completed	
Last Edited 25/03/2020	**Condition category** Surgery	

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
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

Study design
Prospective randomised case controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
Outcome of surgery, patient questionnaire.

Secondary outcome measures
Not provided at time of registration

Overall study start date
19/06/2003

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

Age group
Not Specified

Sex
Not Specified

Target number of participants
150

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

England

United Kingdom

Study participating centre
Hull Royal Infirmary
Hull
United Kingdom
HU3 2JZ

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
The North and South Bank Research and Development Consortium (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