

Pupil dilation prior to cataract surgery with a pledget sponge - a randomised controlled trial.

Submission date 30/09/2005	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 30/09/2005	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 23/07/2009	Condition category Surgery	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mr Austin McCormick

Contact details
Department of Opthamology
Arrowe Park Hospital
Arrowe Park Road
Upton
Wirral
United Kingdom
CH49 5PE

Additional identifiers

Protocol serial number
N0280141214

Study information

Scientific Title

Study objectives

Is pledget sponge soaked in dilating drops as effective as simple repeated drop administration in producing pupil dilation?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from local medical ethics committee

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Surgery: Cataract

Interventions

Randomised controlled trial.

1. Pledget sponge.
2. Repeated drop administration.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

tropicamide phenylephrine atropine

Primary outcome(s)

Pupil diameter

Key secondary outcome(s)

Pain or discomfort on administration of drops or pledget assessed using a visual analogue scale

Completion date

01/08/2004

Eligibility

Key inclusion criteria

Plan for 40 patients per group, on average 6 patients per list means approximately 14 lists, 2 Lists per week over 7 weeks.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

Key exclusion criteria

Previous eye disease likely to cause a small pupil

Date of first enrolment

01/05/2004

Date of final enrolment

01/08/2004

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

Department of Opthamology

Wirral

United Kingdom

CH49 5PE

Sponsor information**Organisation**

Department of Health

Funder(s)**Funder type**

Hospital/treatment centre

Funder Name

Wirral Hospitals NHS Trust (UK)

Funder Name

NHS R&D Support Funding

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	01/08/2006		Yes	No