ISRCTN63768137 https://doi.org/10.1186/ISRCTN63768137

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

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

Study design
Randomised controlled trial

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
Randomised controlled trial.
1. Pledget sponge.
2. Repeated drop administration.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
tropicamide phenylepherine atropine

Primary outcome measure

Pupil diameter

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

Overall study start date
01/05/2004

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

Age group
Not Specified

Sex
Not Specified

Target number of participants
80

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
England

United Kingdom

Study participating centre
Department of Opthamology
Wirral

United Kingdom
CH49 5PE

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

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

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Wirral Hospitals NHS Trust (UK)

Funder Name
NHS R&D Support Funding

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?
Results article	results	01/08/2006		Yes	No