

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

<b>Submission date</b>	<b>Recruitment status</b>	<input type="checkbox"/> Prospectively registered
30/09/2005	No longer recruiting	<input type="checkbox"/> Protocol
<b>Registration date</b>	<b>Overall study status</b>	<input type="checkbox"/> Statistical analysis plan
30/09/2005	Completed	<input checked="" type="checkbox"/> Results
<b>Last Edited</b>	<b>Condition category</b>	<input type="checkbox"/> Individual participant data
23/07/2009	Surgery	

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Mr Austin McCormick

### Contact details

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## 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

**Study design**

Randomised controlled trial

**Primary study design**

Interventional

**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 Ophthalmology

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?
<a href="#">Results article</a>	results	01/08/2006		Yes	No