

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

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

**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 phenylephrine 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 Ophthalmology

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