

# The effect of hyaluronidase on dispersal of local anaesthetic solution after sub-Tenon's injection

<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> 11/12/2008	<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**  
N0436146624

## Study information

## Scientific Title

### Study objectives

To study the difference in distribution of anaesthetic fluid with and without hyaluronidase after sub-Tenon's block using B scan ultrasonography. Patients will be randomised to a group receiving local anaesthetic plus hyaluronidase. An ultrasound scan of the orbit will be performed prior to injection and 1, 3 and 5 minutes after injection to assess dispersal of local anaesthetic solution. The maximum depth of the local anaesthetic solution will be used to compare groups. The quality of the block will also be assessed in terms of akinesia, patient pre-operative pain scores and surgical assessment of the block.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Not provided at time of registration

### Study design

Randomised controlled trial

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Not specified

### Study type(s)

Not Specified

### Participant information sheet

### Health condition(s) or problem(s) studied

Surgery: Anaesthesia

### Interventions

1. Anaesthetic fluid with hyaluronidase
2. Anaesthetic fluid without hyaluronidase

### Intervention Type

Procedure/Surgery

### Phase

Not Specified

### Primary outcome measure

Ultrasound measured depth of local anaesthetic solution behind the eye at 1, 3 and 5 minutes after the injection.

### **Secondary outcome measures**

Akinesia, pain scores and surgical satisfaction.

### **Overall study start date**

24/03/2004

### **Completion date**

15/06/2004

## **Eligibility**

### **Key inclusion criteria**

Consecutive patients presenting for routine cataract extraction surgery will be approached to enrol in the study. They are mostly elderly patients (from previous studies in Leeds age range 65-80 years)

### **Participant type(s)**

Patient

### **Age group**

Senior

### **Sex**

Not Specified

### **Target number of participants**

Added December 2008: 19

### **Key exclusion criteria**

1. Allergy to local anaesthetic
2. Inability/refusal to give informed consent
3. Any patient with pre existing extra ocular muscle palsy, patients with single eye who could be unable to follow a target so assessment of akinesia would be impossible.

### **Date of first enrolment**

24/03/2004

### **Date of final enrolment**

15/06/2004

## **Locations**

### **Countries of recruitment**

England

United Kingdom

**Study participating centre**  
**Leeds Metropolitan University**  
Leeds  
United Kingdom  
LS9 7TF

## **Sponsor information**

**Organisation**  
Department of Health

**Sponsor details**  
Richmond House  
79 Whitehall  
London  
United Kingdom  
SW1A 2NL  
+44 (0)20 7307 2622  
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**Sponsor type**  
Government

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

## **Funder(s)**

**Funder type**  
Government

**Funder Name**  
Leeds Teaching Hospitals NHS Trust (UK), own account

## **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	01/08/2008		Yes	No