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

Submission date 30/09/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/09/2005	**Overall study status** Completed	
Last Edited 11/12/2008	**Condition category** Surgery	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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 sores 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

Study type(s)
Not Specified

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

Key secondary outcome(s))
Akinesia, pain scores and surgical satisfaction.

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

Healthy volunteers allowed
No

Age group
Senior

Sex
Not Specified

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
United Kingdom

England

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

Sponsor information

Organisation
Department of Health

Funder(s)

Funder type
Government

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

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	01/08/2008		Yes	No