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Comparative efficacy of topical TetraVisc™ versus lidocaine gel in cataract surgery

Submission date	Recruitment status	[_] Prospectively registered
02/06/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
09/07/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
18/11/2009	Eye Diseases	

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
N/A

Study information

Scientific Title

Comparative efficacy of topical TetraVisc™ versus lidocaine gel in cataract surgery: randomised, multi-surgeon, controlled clinical trial

Study objectives
To compare the clinical efficacy of lidocaine 2% gel with tetravisc drops for cataract surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Review Board/Ethics Committee of University of Florida (ref: 2007-007)

Study design
Randomised multi-surgeon controlled clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Cataract/topical anaesthesia

Interventions
The patients were randomised by block randomisation (randomly assigned by computer generated numbers) to receive either TetraVisc™ (Tetracaine hydrochloride 0.5%, OCuSOFT) eye drops or lidocaine (Xylocaine 2% jelly, Astra) consecutively. Five doses of TV or LG were applied every 5 minutes, 20 minutes prior to surgery. No intravenous or oral sedation was used as pre-medication.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
TetraVisc™, lidocaine gel

Primary outcome measure
Grading intra-operative pain using a 0 to 10 Visual Analogue Scale (VAS) within 10 minutes of completion of surgery.

Secondary outcome measures
1. Grading the surgical experience as 0 - 10 where 0 is poor co-operation and 10 is excellent co-operation
2. Supplemental anaesthesia used
3. Intra-operative complications

Measured at the end of surgery.

Overall study start date
01/01/2006

Completion date
30/11/2006

Eligibility

Key inclusion criteria
1. Patients undergoing cataract surgery under topical anaesthesia
2. Aged 50 - 80 years, no gender preference

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
122

Key exclusion criteria
1. Unwillingness to have topical anaesthesia
2. High anxiety
3. Dementia or mental instability
4. Deafness
5. Movement disorders
6. Hyperanxiety
7. Inability to complete the Visual Analogue Scale (VAS) of pain line (for example, confusion, communication barriers, visual impairment)
8. Any reported allergy to lidocaine or tetracaine

Date of first enrolment
01/01/2006

Date of final enrolment
30/11/2006

Locations

Countries of recruitment
United States of America

Study participating centre
580 W 8th Street, Tower 2, 3rd Floor
Jacksonville
United States of America
32209

Sponsor information

Organisation
University of Florida (USA)

Sponsor details
Department of Ophthalmology
College of Medicine
580 W 8th Street, Tower 2, 3rd Floor
Jacksonville
United States of America
32209

Sponsor type
University/education

ROR
https://ror.org/02y3ad647

Funder(s)

Funder type
University/education

Funder Name
University of Florida (USA) - Department of Ophthalmology

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	17/08/2009		Yes	No