

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

Submission date 02/06/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 09/07/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 18/11/2009	Condition category Eye Diseases	<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

Protocol serial number
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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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)

ROR

<https://ror.org/02y3ad647>

Funder(s)**Funder type**

University/education

Funder Name

University of Florida (USA) - Department of Ophthalmology

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	17/08/2009		Yes	No