

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

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

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof K V Chalam

**Contact details**  
580 W 8th Street, Tower 2, 3rd Floor  
Jacksonville  
United States of America  
32209

## 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?
<a href="#">Results article</a>	results	17/08/2009		Yes	No