

# Umbilical cord serum therapy in acute ocular chemical burns

**Submission date**  
04/06/2010

**Recruitment status**  
No longer recruiting

Prospectively registered

Protocol

**Registration date**  
05/07/2010

**Overall study status**  
Completed

Statistical analysis plan

Results

**Last Edited**  
06/04/2011

**Condition category**  
Injury, Occupational Diseases, Poisoning

Individual participant data

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

## Contact information

**Type(s)**  
Scientific

**Contact name**  
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## Additional identifiers

## Study information

**Scientific Title**  
Evaluation of umbilical cord serum therapy in acute ocular chemical burns: a prospective, double-blind, randomised controlled trial

**Study objectives**

The primary objectives of therapy in a case of acute ocular chemical burns are promotion of epithelialisation, reduction of inflammation, support of the reparative processes and prevention of complications. The standard medical treatment used in acute ocular chemical burns comprises of topical steroids, topical antibiotics, mydriatic cycloplegic, anti-glaucoma therapy, citrate and ascorbate. Autologous serum drops have been shown to be effective in the treatment of various ocular surface disorders including neurotrophic keratitis, severe dry eye, persistent epithelial defects and recurrent corneal erosions. Umbilical cord serum has been shown to be safe and effective in the treatment of neurotrophic keratitis, dry eye syndrome and persistent epithelial defects.

Both autologous serum and umbilical cord serum owe their efficacy to the presence of various growth factors like epidermal growth factor (EGF), acidic and basic fibroblast growth factor (FGF), platelet-derived growth factor, hepatocyte growth factor, vitamin A, transforming growth factor  $\beta$  (TGF- $\beta$ ), substance P, IGF-1 (insulin like growth factor-1), nerve growth factor (NGF), fibronectin and serum antiproteases such as  $\alpha$ 2 macroglobulin. The concentrations of EGF, TGF- $\beta$  and NGF are several times higher in umbilical cord serum than peripheral blood serum. In the present study we tested the hypothesis, that umbilical cord serum with its higher concentration of these growth factors may promote an early healing of the ocular surface in cases of chemical burns.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

All India Institute of Medical Sciences, New Delhi, India approved on the 15th of September 2005

### **Study design**

Double blind prospective randomised controlled clinical trial

### **Primary study design**

Interventional

### **Study type(s)**

Treatment

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

Acute chemical ocular burns

### **Interventions**

1. Patients were started on standard medical therapy consisting of:

1.1. Topical ofloxacin hydrochloride 0.3% 6-hourly

1.2. Topical prednisolone acetate 1% 2-hourly

1.3. Topical homatropine 2% three times daily (tds)

1.4. Topical ascorbate 10% 2-hourly

1.5. Topical citrate 10% 2-hourly

1.6. Oral vitamin C 500 mg four times daily (qid)

1.7. Preservative free topical lubricants 2-hourly

1.8. Topical anti-glaucoma medications (if required) in the form of timolol maleate eye drops

0.5% bid and/or oral acetazolamide 250 mg tds

2. Patients were then divided into three groups:
- 2.1. Group I received 20% umbilical cord serum drops 10 times a day
  - 2.2. Group II received 20% autologous serum drops 10 times a day
  - 2.3. Group III received artificial tear drops (0.5% hydroxypropylmethylcellulose and 0.3% glycerin) 10 times a day

### **Intervention Type**

Other

### **Phase**

Not Applicable

### **Primary outcome(s)**

Patients were followed up on day 1, day 3, day 7, day 14, day 21 and at the end of 1 month, 2 months and 3 months. Total duration of follow up in all three groups was 3 months.

Parameters assessed were at each follow-up included:

1. Pain score
2. Best corrected visual acuity
3. Limbal ischaemia
4. Epithelial defect
5. Corneal clarity and vascularisation
6. Tear film status (Schirmer, TBUT)
7. Intraocular pressure (IOP)
8. Symblepharon formation

### **Key secondary outcome(s)**

Complications arising from injury and/or treatment

### **Completion date**

01/07/2007

## **Eligibility**

### **Key inclusion criteria**

1. Patients with acute ocular chemical burns (grade III, IV and V according to Dua classification) presenting within three weeks of injury
2. Either sex, aged 16 - 50 years

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

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Sex**

All

**Key exclusion criteria**

1. Patients with grade I, II and VI injury
2. Impending perforation

**Date of first enrolment**

01/09/2005

**Date of final enrolment**

01/07/2007

**Locations****Countries of recruitment**

Australia

India

**Study participating centre**

**Centre for Eye Research Australia**

Melbourne

Australia

3002

**Sponsor information****Organisation**

Dr Rajendra Prasad Centre for Ophthalmic Sciences (India)

**ROR**

<https://ror.org/02dwcqs71>

**Funder(s)****Funder type**

Hospital/treatment centre

**Funder Name**

Dr RP Centre for Ophthalmic Sciences (India) - Hospital infrastructure and resources

**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?
<a href="#">Results article</a>	results	25/02/2011		Yes	No