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Umbilical cord serum therapy in acute ocular chemical burns

Submission date	Recruitment status
04/06/2010	No longer recruiting
Registration date	**Overall study status**
05/07/2010	Completed
Last Edited	**Condition category**
06/04/2011	Injury, Occupational Diseases, Poisoning

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

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), platlet-derived growth factor, hepatocyte growth factor, vitamin A, transforming growth factor ß (TGF-ß), substance P, IGF-1 (insulin like growth factor-1), nerve growth factor (NGF), fibronectin and serum antiproteases such as a2 macroglobulin. The concentrations of EGF, TGF-ß 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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Not available in web format, please contact Dr Manik Goel [manikgoel_aiims99@yahoo.com] to request a patient information sheet

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 measure
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

Secondary outcome measures
Complications arising from injury and/or treatment

Overall study start date
01/09/2005

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

Age group
Adult

Sex
Both

Target number of participants
33 eyes of 32 patients

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)

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Sponsor type
Hospital/treatment centre

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

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	25/02/2011		Yes	No