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Comparing cultured limbal stem cell transplantation (CLET) with direct limbal lenticule transplantation (SLET) in eyes with total limbal stem cell deficiency due to ocular burns

Submission date
30/08/2018

Recruitment status
No longer recruiting

Registration date
10/09/2018

Overall study status
Completed

Last Edited
13/07/2021

Condition category
Eye Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
In India, a calcium hydroxide paste called chuna is used as an additive to chewing tobacco, usually in small quantities. In the past few years, companies have started marketing chuna in the form of pouches. If these pouches burst, they can cause severe ocular burns, which is a type of eye injury. Ocular burns account for around 7-18% of eye injuries and the majority of victims are young.
Ocular burns can lead to total limbal stem cell deficiency (LSCD) - this means that there are no cells left to repair the eye injury. There are two types of surgery available to fix this, which are called CLET and SLET. This study aims to compare the effectiveness of these types of surgery on ocular burn victims with LSCD.

Who can participate?
People with LSCD due to ocular burns (thermal or chemical) who are attending the Cornea Services of the Dr. R. P. Centre for Ophthalmic Sciences in New Delhi, India

What does the study involve?
Participants will be randomly allocated to receive either CLET or SLET. Participants will receive various examinations, including an examination of the injury and a complete eye examination, before the study and for a period of 3 years after the surgery.

What are the possible benefits and risks of participating?
Participants in both groups will benefit, as both surgical procedures should improve their ocular surface and enhance their vision. There are no known risks to participating in this study.

Where is the study run from?
Dr. R. P. Centre for Ophthalmic Sciences, New Delhi (India)

When is the study starting and how long is it expected to run for?
June 2015 to December 2018

Who is funding the study?
Department of Science and Technology (DST), Government of India (India)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
D382

Study information

Scientific Title
Comparison of autologous cultured limbal stem cells on amniotic membrane transplant (CLET) versus limbal lenticule transplantation alone (SLET) in the management of total limbal stem cell deficiency due to ocular burns: A randomised controlled clinical trial

Study objectives
Limbal stem cell deficiency due to ocular burn is characterized by conjunctival ingrowth, chronic inflammation and epithelial defects. The sequelae of this includes corneal neovascularization, scarring, symblepharon formation, and severe dry eye. There are no randomised controlled trials in literature which have compared the results of in vivo direct limbal lenticule (lenticule-LSCT) with amniotic membrane transplantation versus cultured limbal stem cells on amniotic membrane in cases of partial limbal stem cell deficiency due to ocular burns. We herein propose to undertake this study to evaluate if lenticule-LSCT is as efficacious as cultured limbal stem cells, thus ameliorating the cost of cultivation techniques and wider application in peripheral centres lacking expensive laboratory facilities and manpower.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Institutional Committee for Stem Cell Research (IC-SCR), All India Institute of Medical Sciences, Delhi, India, 02/05/2015, IC-SCR/23/14(R2).

Primary study design
Interventional

Study design
Interventional prospective randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Chronic ocular burns with total limbal stem cell deficiency (LSCD)

Interventions
Participants will be randomly allocated into two groups using a table of random numbers. Group 1 will receive direct limbal lenticule with an amniotic membrane graft (Lenticule-LCST) transplantation. Group 2 will receive amniotic membrane with cultured limbal stem cells transplantation. Participants in both groups will receive an examination of the injury and any preliminary treatment, a basic ocular examination and detailed ophthalmic examination, along with having clinical photographs taken. The ocular examination will involve examination of the following:
1. Vision and visual acuity (UCVA and BCVA) of both eyes
2. Adnexa
3. Extent of conjunctival involvement in clock hours
4. Limbal ischemia
5. Presence or absence of symblepharon
6. The cornea will be examined for:
6.1. Extent of haze
6.2. Grade of clarity
6.3. Amount of conjunctivalisation
6.4. Neovascularisation
Participants in both groups will also receive the following pre-operative investigations:
1. Corneal sensation
2. Fluorescein staining
3. Conjunctival impression cytology from corneal surface
4. Clinical photography
5. Impression cytology
6. Corneal epithelial stem cell markers like K3, ABCG2 (if possible)
7. Ultrasonic 9-point pachymetry
8. Ultrasound biomicroscopy
9. Intraocular pressure
10. Schirmer's test (I and II)
There is a 3 year follow-up period for all participants.

Intervention Type
Procedure/Surgery

Primary outcome(s)
The following are assessed at the baseline, and 3, 6, 12, 24 and 36 months after the operation:
1. Degree of inflammation, assessed using the grading score for inflammation (conjunctival hyperaemia)
2. Degree of corneal vascularisation, assessed using the grading score for corneal vascularisation

Key secondary outcome(s)
The following are assessed at the baseline, and 3, 6, 12, 24 and 36 months after the operation:
1. Improvement in tear secretions, assessed using Schirmer's test
2. Ocular surface status, assessed using the overall grading for ocular surface parameters

Completion date
08/12/2018

Eligibility

Key inclusion criteria
1. Unilateral cases of total limbal stem cell deficiency (LSCD) due to ocular burns (thermal or chemical), diagnosed by the presence of clinical signs of total LSCD (in clock hours), including:
1.1. Loss of normal anatomy
1.2. Epithelial haze
1.3. Superficial subepithelial vascularisation
1.4. Persistent or recurrent epithelial defects
1.5. Epithelial and stromal inflammation
1.6. Fluorescein staining
1.7. Loss of limbal palisades of Vogt
2. Attending Cornea Services of Dr. R. P. Centre for Ophthalmic Sciences in New Delhi

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
All

Sex
All

Key exclusion criteria
1. Patients who have undergone prior intraocular/extraocular surgery
2. Bilateral involvement
3. Refuse to provide consent
4. Unavailable for follow up

Date of first enrolment
01/09/2015

Date of final enrolment

31/08/2017

Locations

Countries of recruitment
India

Study participating centre
Dr R.P.Centre for Ophthalmic Sciences, All India Institute of Medical Sciences.
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Sponsor information

Organisation
All India Institute of Medical Sciences

ROR
https://ror.org/02dwcqs71

Funder(s)

Funder type
Not defined

Funder Name
Science and Research Engineering Board, Department of Science & Technology, Government of India

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		09/04/2019	09/04/2019	No	No