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Corneal tattooing for corneal opacities

Submission date	Recruitment status	[_] Prospectively registered
20/10/2017	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
26/10/2017	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
25/11/2020	Eye Diseases	

Plain English summary of protocol

Background and study aims
Corneal (the front part of the eye that covers the pupil and iris) tattooing is one of the options offered to patients with corneal opacities (problems that lead to scarring or clouding of the cornea). However, there are many other types of treatments that have impacted he popularity of corneal tattoing. Various tattooing methods have been used such as: chemical dyeing with gold or platinum chloride, and nonmetallic tattooing with Indian ink, Chinese ink, lamp black, and other organic dyes. The aim of this study is to examine if treatment of corneal opacities by painting them with Rotring Chinese ink.

Who can participate?
Patients with superficial or deep corneal opacity causing severe disfigurement or those who are blind.

What does the study involve?
The procedure is carried out in the operating room under sterile conditions by one surgeon (AHA) under topical anesthesia in all patients. Corneal epithelium is not removed. The ink is administered by multiple corneal injections with ink pre-loaded from a sterile cup. The number of injections is determined by the density of the scar and ranges from 4-8 injections. Saline solution is applied to irrigate the corneal surface to wash away excess ink and allow good visualization between injections. Contact lens are then applied and removed after one week.

What are the possible benefits and risks of participating?
Participants may benefit from an improvement in cosmetic appearance of the eyes. There are no expected risks as the maneuver was tried on rabbits before so there is no risk of dissemination or long term complication on the cornea.

Where is the study run from?
Sohag University (Egypt)

When is the study starting and how long is it expected to run for?
June 2016 to June 2017

Who is funding the study?
Sohag University Hospital (Egypt)

Who is the main contact?
Dr Engy Mostafa

Contact information

Type(s)
Scientific

Contact name
Dr Engy Mostafa

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Additional identifiers

Protocol serial number
1

Study information

Scientific Title
Outcomes of corneal tattooing by Rotring Painting Ink in disfiguring corneal opacities

Study objectives
The aim of this study is to examine if treatment of corneal opacities by painting them with Rotring Chinese ink.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical Committee of Faculty of Medicine Sohag University, 25/07/2016

Primary study design
Interventional

Study design
Prospective interventional non-comparative clinical study

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Total corneal leukomas

Interventions
Participants receive conreal tatooing. The procedure is carried out in the operating room under sterile conditions by one surgeon (AHA) under topical anesthesia in all patients. Corneal epithelium is not removed. The ink is administered by multiple transepithelial intrastromal corneal injections using a 30 gauge needle attached to an insulin syringe with ink pre-loaded from a sterile cup. The bevel of the needle is up and administered tangential to the corneal surface to end up in approximately in the mid stroma avoiding accidental perforation of the cornea. The number of injections is determined by the density of the scar and ranged from 4-8 injections. Saline solution is applied to irrigate the corneal surface to wash away excess ink and allow good visualization between injections. Contact lens are then applied and removed after one week.

Postoperatively, moxiflocacin and 1% prednisolone acetate eyedrops are prescribed five times per day for two weeks. NSAID are prescribed twice daily for 3 days. Participants are followed up at one day, one week, one, three and six months. Photographs are taken after one month for comparison. Retreatment is done when needed as in inadequate coloration from the start or fading of the color.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Corneal opacity being tattooed is measured using the slitlamp to judge fading and photographing the eyes at day one, one week, and one month.

Key secondary outcome(s)
Postoperative complications is measured using slitlamp at day one, week one and month one and six months.

Completion date
30/06/2017

Eligibility

Key inclusion criteria
1. No specific age
2. No specific gender
3. Superficial or deep corneal opacity causing severe disfigurement
4. Blind eyes

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group

All

Sex
All

Total final enrolment
53

Key exclusion criteria
1. Chronically inflamed eyes
2. Severe corneal calcification or neovascularization
3. Phthisical eyes
4. Anterior

Date of first enrolment
01/09/2016

Date of final enrolment
30/12/2017

Locations

Countries of recruitment
Egypt

Study participating centre
Sohag University
Sohag
Egypt
82525

Sponsor information

Organisation
Sohag Univerity Hospital

ROR
https://ror.org/02wgx3e98

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Sohag University Hospital

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Engy Mohamed Mostafa at engymostafa@yahoo.com.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	25/06/2018	25/11/2020	Yes	No