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The healing effect of Panthenol eye drops on eye wounds from laser vision correction surgeries

Submission date
10/10/2018

Recruitment status
No longer recruiting

Registration date
17/10/2018

Overall study status
Completed

Last Edited
05/04/2019

Condition category
Eye Diseases

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

Plain English summary of protocol

D-Panthenol is the precursor of vitamin B5. It has a proven regenerative power on damaged body surfaces, such as burns and wounds. There are several preparations assigned for eye care containing D-Panthenol. It is added to artificial tears formula to enhance its lubricant and regenerative power.
One of the vision correction procedures is surface ablation, where the surface of the cornea is left with an epithelial defect. It is controlled and designed according to required treatment. To test its regenerative power, D-Panthenol was used on one eye and compared its effect to other similar tear drops formula, not including it, in the fellow eye.
The speed of healing will be compared in the 2 eyes of all participants.

Background and study aims
Panthenol is available and widely used in various skin ointments, creams and gels. It has proved to be a successful treatment for burns and superficial skin wounds. Panthenol eye drops are also available, which can have the same benefits as on the skin in the case of injury to the eye surface. Surface ablation is a type of vision correction procedure that can sometimes leave the surface of the eye with a defect that heals within a few days. This study aims to look at the healing effect of panthenol drops on these surface abrasions.

Who can participate?
All patients visiting The Eye Consultants Centre in Jeddah for eye sight correction surgery

What does the study involve?
All participants will receive the surface ablation procedure as part of their usual treatment. They will then receive conventional treatment in one eye, and in the other they will additionally receive panthenol eye drops for 2 months following the surgery. Which eye receives which treatment is to be allocated at random. Participants will have examinations for the first 3 days after surgery, then weekly for 4 weeks, and then after 2 months.

What are the possible benefits and risks of participating?
The possible benefit of participating is that panthenol may increase the healing time after

surgery. There are no known risks to participants taking part in this study other than the standard risks associated with laser ablation procedures.

Where is the study run from?
The Eye Consultants Centre, Jeddah (Saudi Arabia)

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

Who is funding the study?
Self-funded

Who is the main contact?
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Contact information

Type(s)
Scientific

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Protocol serial number
005

Study information

Scientific Title
The effect of D-panthenol on corneal epithelial healing after surface laser ablation

Study objectives
D-Panthenol provides faster and better healing of corneal epithelial defects, than artificial tear drops alone.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Eye Consultants Center Ethical Committee, Jeddah, Saudi Arabia, 19/04/2016 (no reference number available)

Study design
Interventional prospective randomised controlled study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Epithelial corneal defects, created iatrogeniccally during surface laser ablation procedure

Interventions
Patients serve as their own control, with one eye randomly allocated to receive D-panthenol in propyl-methyl-cellulose eye drops four times daily for 2 months, and the other to receive carboxy methyl cellulose eye drops at the same dosage and duration. The first 23 patients will receive D-panthenol in their right eye and the next 22 patients will receive D-panthenol in their left eye.
All eyes receive antibiotic eye drops (gatifloxacin) four times per day for 3 days (phase 1 of healing). During phase 2 (day 4 until the end of month 2) of healing, antibiotic eye drops will be replaced with topical corticosteroids drops (rimexolone 1%) to be used four times per day.
During phase 1, patients are examined daily for 3 days. During phase 2, patients are examined weekly for 1 month, and then at at the end of month 2.
For purpose of randomization, first 23 patients would receive D-panthenol in right eye and the next 22 patients would receive D-panthenol in left eye.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
D-Panthenol eye drops (Augé Vitamin TM)

Primary outcome(s)
Rate of epithelial healing, assessed by:
1. Rate of epithelial closure, assessed on a slit lamp bio-microscope on days 1, 2 and 3
2. Corneal haze, assessed on a slit lamp bio-microscope at weeks 1, 2, 3 and 4, and the end of month 2

Key secondary outcome(s))
1. Effect of D-panthenol on visual acuity, assessed by:
1.1. Uncorrected visual acuity (UCVA) using a Snellen's chart at days 1, 2 and 3, weeks 1, 2, 3 and

4, and the end of month 2
1.2. Residual subjective refraction, assessed using an auto-refractometer at weeks 1, 2, 3, and 4, and the end of month 2
2. Subjective comfort with or without D-panthenol, assessed by asking participants to rate comfort out of 5, with 0 indicating "no discomfort" and 5 being "severe intolerant symptoms", at weeks 1, 2, 3 and 4, and the end of month 2

Completion date
31/01/2017

Eligibility

Key inclusion criteria
1. Ametropia
2. Seeking laser vision correction
3. Best corrected visual acuity 20/20 or better in each eye
4. Eyes fit for laser ablation procedure and otherwise normal

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Previous ocular surgery
2. Concomitant ocular morbidity

Date of first enrolment
01/05/2016

Date of final enrolment
01/11/2016

Locations

Countries of recruitment
Saudi Arabia

Study participating centre
The Eye Consultants Center
PO Box 15637

Jeddah
Saudi Arabia
21454

Sponsor information

Organisation
The Eye Consultants Center

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

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 Islam Hamdi (islammhamdi@hotmail.com). All data are preserved in their personal files in The Eye Consultants Centre. Files are maintained for 3 years after the last patient visit. The master sheet and case report forms related to the study are preserved with Dr. Hamdi. Data related to the study (e.g. medical data) may be available by contacting Dr. Hamdi. Personal data not related to the nature of the study (e.g. names, addresses, etc..) will not be released, due to the privacy of the participants. The release of data for the purpose of research was agreed upon in the consent forms for participants enrolling in the study.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	12/11/2018	05/04/2019	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes