ISRCTN21394752 https://doi.org/10.1186/ISRCTN21394752

Analgesic eye drops for pain control after a refractive procedure

Submission date
05/03/2021

Recruitment status
No longer recruiting

Registration date
08/03/2021

Overall study status
Completed

Last Edited
13/01/2022

Condition category
Surgery

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

Plain English summary of protocol

Background and study aims
Photorefractive keratectomy is a well-established safe method of surgery that uses a laser to treat vision problems caused by refractive errors. Pain in the first few days after the procedure can be annoying to the patients, and there are many drugs that could be used topically (eye drops) to control this pain. However, they have other unwanted effects like prolonging the time of healing after the procedure. The aim of this study is to find out if topical nalbuphine hydrochloride is effective in controlling postoperative pain, and which concentration is more effective at preventing pain and whether this pain control is associated with any unwanted side effects. Nalbuphine hydrochloride is a well known potent analgesic used after many major surgeries, it will be reconstituted into eye drops form to be used topically in the first 3 days after the surgery.

Who can participate?
Patients aged over 20 who are going to have refractive surgery to correct a low or moderate error of refraction

What does the study involve?
The study involves patients using eye drops from a pre-prepared (analgesic eye drops) bottle without knowing its true content in the first 3 days following the refractive procedure. Some patients will receive a bottle with a certain concentration of the analgesic, others will receive a higher concentration of the analgesic and the remaining patients will receive only artificial tears. The patients are asked to record their pain and the number of times they use the eye drops in the first 3 days and they attend a daily examination in the first 8 days following the procedure. The last follow-up visit is at the end of the third postoperative month to measure the final visual acuity and refractive outcome.

What are the possible benefits and risks of participating?
The participants are expected to have better pain control in the first days after the refractive procedures. Possible risks include delayed healing which can be assessed by daily examination of the patients.

Where is the study run from?
Delta Medical Center (Egypt)

When is the study starting and how long is it expected to run for?
April 2019 to November 2020

Who is funding the study?
Delta Medical Center (Egypt)

Who is the main contact?
Dr Hala Mattout
HKMtoot@medicine.zu.edu.eg

Contact information

Type(s)
Scientific

Contact name
Dr Hala Mattout

ORCID ID
https://orcid.org/0000-0003-4809-6745

Contact details
16 Ali ben Abitaleb Street
Velal Elgamaa
Zagazig
Egypt
44111
+20 (0)01227112632
HKMtoot@medicine.zu.edu.eg

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
4NPR19

Study information

Scientific Title

The use of topical nalbuphine in different concentrations to control pain after photorefractive keratectomy

Study objectives
Topical nalbuphine hydrochloride eye drops relieve pain after photorefractive keratectomy and this effect is higher with a 2 mg/ml concentration than with a 1 mg/ml concentration.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 16/6/2019, Delta Medical Center Research Ethics Committee (Alexandria Street from Gesr Elnile Street, Mitghamr, Egypt; +20 (0)504906761; healthresethics@deltahealth.online), ref: 4NPR19

Study design
Single-center interventional double-blinded randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Pain following photorefractive keratectomy procedure

Interventions
The patients are randomized using computer-generated randomization tables to three groups: topical nalbuphine postoperative with a concentration of 2 mg/ml (group A), topical nalbuphine with a concentration of 1 mg/ml (group B) and a control group receiving artificial tears only (group C).

The patients are asked to record their pain and the number of times they use the eye drops in the first 3 days and they attend a daily examination in the first 8 days following the procedure. The last follow-up visit is at the end of the third postoperative month to measure the final visual acuity and refractive outcome.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Nalbuphine hydrochloride

Primary outcome measure
Pain measured using a numeric rating scale (recording the maximum pain level) in the first 3 postoperative days

Secondary outcome measures
1. Number of analgesic eye drops applications recorded by patients in the first 3 postoperative days
2. Time needed for complete epithelial healing assessed by slit-lamp examination daily in the first 8 postoperative days
3. Best corrected visual acuity (converted to LogMAR) measured by Landolt chart at the end of the third postoperative month
4. Refraction measured by autorefractometer at the end of the third postoperative month

Overall study start date
01/04/2019

Completion date
15/11/2020

Eligibility

Key inclusion criteria
1. Age above 20 years
2. Error of refraction is less than 4 D spherical equivalent
3. Minimum corneal thickness is more than 480 microns
4. Absence of collagen diseases
5. Absence of corneal surface abnormalities
6. Absence of ocular diseases other than the refractive error
7. No history of concurrent use of systemic or topical analgesics

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
200

Total final enrolment
189

Key exclusion criteria
1. Age below 20 years
2. Error of refraction is more than 4 D spherical equivalent
3. Minimum corneal thickness is less than 480 microns
4. Presence of collagen diseases
5. Presence of corneal surface abnormalities
6. Presence of ocular diseases other than the refractive error
7. History of concurrent use of systemic or topical analgesics

Date of first enrolment
01/07/2019

Date of final enrolment
30/07/2020

Locations

Countries of recruitment
Egypt

Study participating centre
Delta Eye and Laser Center
Mitghamr City
Gesr Elnile street
Dakahleya Governorate
Egypt
-

Sponsor information

Organisation
Delta Medical Center

Sponsor details
Mitghamr City
Gesr Elnile Street
Dakahleya Governorate
Egypt
35612
+20 (0)504906761
healthresethics@deltahealth.online

Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Delta Medical Center

Results and Publications

Publication and dissemination plan
Planning publication in a high impact peer-reviewed journal

Intention to publish date
01/02/2022

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 Hala Mattout (HKMtoot@medicine.zu.edu.eg). The data available will be in the form of Excel sheets containing recorded pain scores, healing time and other outcome measures related to the research. Consents are obtained from patients. Data are shared with the statistical analysis team to obtain the results of the study

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			01/04/2021	No	Yes
Participant information sheet			01/04/2021	No	Yes
Protocol file			01/04/2021	No	No
Results article		12/01/2022	13/01/2022	Yes	No