Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effect of Dexamethasone soaked nasalpack on postoperative pain of patients undergoing Dacryocystorhinostomy surgery

Protocol summary

Study aim
Determining the effect of topical dexamethasone on postoperative pain in patients under dacryocystorhinostomy

Design
Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 112 patients. Randomaize.com was used for randomization.

Settings and conduct
In Khatam Al-Anbia Medical Center in Mashhad, after obtaining the patient's informed consent, they are randomly divided into two groups of intervention and control using computerized randomization software. For the intervention group, at the end of the operation, a dexamethasone-impregnated tampon is placed in the upper horn of the middle concha. In the control group, a tampon impregnated with normal saline is placed in the same place. Patients are asked in both groups in recovery and after entering the wards 3, 6, 12, 18 and 24 hours about their pain intensity with a verbal rating scale and also the amount of analgesic if it is used by persistant pain.

Participants/Inclusion and exclusion criteria
Inclusion criteria:Age between 18 and 75 years and able to speak Persian, Patient candidate for dacryocystorhinostomy surgery, Patients with class 1 and 2 anesthesia (ASA), no history of known and confirmed psychological disease, no history of current seizures, no history of alcohol or drug abuse based on history, no use of any analgesics in the 24 hours before surgery.
Exclusion criteria: Any unusual complication during surgery (such as heavy bleeding during surgery, prolongation of surgery time (more than 75 minutes) and cardiopulmonary resuscitation during and after surgery

Intervention groups
For the intervention group, at the end of the operation, a dexamethasone-impregnated tampon is placed in the upper horn of the middle concha. In the control group, a tampon impregnated with normal saline is placed in the same place.

Main outcome variables
Pain in the first 24 hours after surgery

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210113050021N1**
Registration date: **2021-02-02, 1399/11/14**
Registration timing: **registered_while_recruiting**

Last update: **2021-02-02, 1399/11/14**
Update count: **0**

Registration date
2021-02-02, 1399/11/14

Registrant information

Name
Sara Jamali

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 3728 9911

Email address
ocean_jamali@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-01-09, 1399/10/20

Expected recruitment end date
2022-01-10, 1400/10/20

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Dexamethasone soaked nasalpack on postoperative pain of patients undergoing Dacryocystorhinostomy surgery

Public title

Effect of Dexamethasone soaked nasalpack on postoperative pain of patients undergoing Dacryocystorhinostomy surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 18 and 75 years old and able to speak Persian, patient candidate for dacryocystorhinostomy surgery, patients with class 1 and 2 anesthesia (ASA), no history of systemic hypertension based on history, no history of known and confirmed Psychological disease based on history, no history of current seizures based on history, no history of alcohol or drug abuse, no use of any painkillers in 24 hours before surgery

Exclusion criteria:

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **112**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple personal randomization will be done using random numbers table
and www.randomization.com website. Randomization concealment will be done using closed envelopes. The envelopes will be prepared and printed by one of the members of the research team and random numbers with the help of Randomaization.com and will be placed inside the envelope. The envelopes are closed and the contents cannot be seen from the outside. Then, the purpose of the study will be explained to the person who meets the inclusion criteria and if the person wishes and signs the informed consent form, takes an envelope and then opens it and enters the intervention or control group based on the contents of the envelope.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients and outcome evaluator are blinded in the trial about how patients are allocated.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mashhad University of Medical Scienses

Street address

Mashhad University of Medical Sciences, Azadi Ave., Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948564

Approval date

2020-11-09, 1399/08/19

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1399.517

Health conditions studied

1

Description of health condition studied

Lacrimal duct obstruction

ICD-10 code

H04.559

ICD-10 code description

Acquired stenosis of unspecified nasolacrimal duct

Primary outcomes

1

Description

Pain in the first 24 hours after surgery

Timepoint

0, 3, 6, 12, 18 and 24 hours after surgery

Method of measurement

Pain intensity is assessed by the grading scale used in the NHS system of Wales University Hospital. This scale has 4 degrees: if the patient expresses complete pain relief, the pain intensity is zero and if the patient expresses severe pain, the patient's pain intensity is 3. At this scale, the patient's pain intensity is asked and the patient's description of the pain experienced is marked in one of four categories: "painless, mild, moderate, severe."

Secondary outcomes

1

Description
Dosage in mg of rescue analgesia (morphine / pethidine / methadone / apotel / ketorolac / indomethacin)
Timepoint
0, 3, 6, 12, 18 and 24 hours after surgery
Method of measurement
questionnaire

2

Description
The interval between the first use of adjuvant painkillers and the end of the operation
Timepoint
In the first 24 hours after surgery
Method of measurement
Patient statement

Intervention groups

1

Description
Intervention group: In the intervention group, at the end of the operation, a dexamethasone-impregnated tampon is inserted in the upper horn of the middle conch.
Category
Treatment - Drugs

2

Description
Control group: In the control group, at the end of the operation, a tampon impregnated with normal saline is inserted in the upper horn of the middle concha.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Khatam Al-Anbia Eye Hospital
Full name of responsible person
Sara Jamali
Street address
Khatam Al-Anbia Eye Hospital, Aboutaleb Intersection
City
Mashhad
Province
Razavi Khorasan
Postal code
9195965919
Phone
+98 51 3728 9911
Email
ocean_Jamali@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Khalil Abnous
Street address
Ghoreyshi building, Daneshgah Ave.
City
Mashhad
Province
Razavi Khorasan
Postal code
9195965919
Phone
+98 51 3845 2474
Email
ramresearch@mums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Sara Jamali
Position
Resident of Ophthalmology
Latest degree
Medical doctor
Other areas of specialty/work
Ophthalmology
Street address
Khatam Al-Anbia Eye Hospital, Aboutaleb Intersection
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
Individual Participant Data Set (IPD): all collected deidentified IPD could be shared.
When the data will become available and for how long
Starting 6 months after publication
To whom data/document is available
People working in academic institutions
Under which criteria data/document could be used
No further criteria.
From where data/document is obtainable
: Khatam al-Anbia Eye Hospital, Aboutaleb Intersection, Mashhad, Iran. 00985137289911 - ocean_jamali@yahoo.com
What processes are involved for a request to access data/document
With a reasonable request, the data would be shared via email.
Comments