Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jul 2026

Evaluation of the effectiveness of Dexmedetomidine in the assessment of postoperative pain in extra ocular muscle surgery in patients with strabismus

Protocol summary

Study aim
The aim of this study was to investigate the effectiveness of Dexmedetomidine in assessing postoperative pain in extra ocular muscle surgery (EOM) in patients with strabismus.

Design
Two arm parallel group randomised clinical trial with control group, double-blinded, phase 3 on 60 patients, the website www.randomization.com was used for randomization

Settings and conduct
In 2020, 60 patients coming to the ophthalmology center of Khatam Al-Anbia Hospital in Mashhad with our inclusion criteria will be enrolled in our study. The study will be double-blind. The patient and the statistical analyzer are unaware of the grouping, a placebo will be used to blind patients and A and B group coding will be used to blind the evaluator. At 4, 8, 12, 24, and 48 hours after the surgery, the amount of pain in both groups will be assessed using a visual analog scale then will be compared.

Participants/Inclusion and exclusion criteria
Inclusion criteria: children over 7 years, no other medical disease, no history of extra ocular muscle surgery , presence of strabismus problems exclusion criteria: liver,heart or renal disease, drug abusers,unable to answer questions of checklist

Intervention groups
"intervention group": in this group, at the end of the surgery, patients will be given 1 microgram per kilogram of their body weight, Dexmedetomidine by the trade name of Precedex, producer HOSPIRA, made in the United States and the distributor is BEHESTAN DAROU, the drug will be poured in the surgical site, tenon, and conjunctiva. "Control group": in this group, the same amount of normal saline produced by SAMEN company will be poured at the surgical site.

Main outcome variables
pain based on visual analog scale

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20200503047291N1**
Registration date: **2020-08-01, 1399/05/11**
Registration timing: **retrospective**

Last update: **2020-08-01, 1399/05/11**
Update count: **0**
Registration date
2020-08-01, 1399/05/11

Registrant information
Name
hamed hosseinikhah
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2019-09-23, 1398/07/01
Expected recruitment end date
2019-12-22, 1398/10/01
Actual recruitment start date
2019-09-23, 1398/07/01
Actual recruitment end date

2020-03-05, 1398/12/15

Trial completion date

2020-03-20, 1399/01/01

Scientific title

Evaluation of the effectiveness of Dexmedetomidine in the assessment of postoperative pain in extra ocular muscle surgery in patients with strabismus

Public title

Evaluation of dexmedetomidine in reducing postoperative ocular pain

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Children over 7 years No other medical problems No history of surgery or manipulation of the extraocular muscles strabismus candidate for extra ocular muscle surgery

Exclusion criteria:

Patients with drug abuse presence of liver,heart or renal disease unable to answer questions of checklist

Age

From **7 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **30**

Actual sample size reached: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization will be done using random numbers table from 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 to the intervention or control group based on the contents of the envelope.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients and outcome assessors are unaware of patient grouping. A placebo will be used for this purpose. The placebo used in this study looks completely similar to the original drug in terms of appearance and packaging type, so that it is impossible to differentiate it from the main drug. The assessor evaluates the outcome of patients in groups called A and B so that it is not known which patient will be in the control group and which patient will be in the intervention group.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee in Research of Mashhad University of Medical Sciences

Street address

Mashhad Medical University, Azadi Square, Mashhad, Iran

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948564

Approval date

2020-04-22, 1399/02/03

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1399.013

Health conditions studied

1

Description of health condition studied

Strabismus

ICD-10 code

H50.9

ICD-10 code description

Unspecified strabismus

2

Description of health condition studied

Esotropia

ICD-10 code

H50.00

ICD-10 code description

Unspecified esotropia

3

Description of health condition studied

Exotropia

ICD-10 code

H50.1

ICD-10 code description

Exotropia

Primary outcomes

1

Description
The amount of postoperative pain
Timepoint
In the designated hours, 4 hours, 8 hours, 12 hours, 24 hours, 48 hours of surgery, the patient's pain rate was assessed using VAS (Visual analogue scale).
Method of measurement
Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In this group, 30 patients with inclusion criteria who need the strabismus surgery according to strabismus surgical protocols with specific standards, were randomly placed in this group. After the surgery, one microgram per kilogram of patients' weight will be poured at the surgical site with the drug dexmedetomidine, which was manufactured under the brand name Precedex by the HASPPIRA factory in the United States.
Category
Treatment - Drugs

2

Description
Control group: In this group, 30 patients with inclusion criteria who need the strabismus surgery according to strabismus surgical protocols with specific standards, were randomly placed in this group. After the surgery, one microgram per kilogram of patients' weight will be poured at the surgical site with the drug Normal salin, which was manufactured by SAMEN company.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Khatamolanbia Hospital
Full name of responsible person
Hamed Hosseinikhahmanshadi
Street address
No. 8, Gharani Street, Vahedi Avenue, Mashhad Town
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
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Street address
Mashhad Medical University, Azadi Street, Mashhad Town
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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
Hamed Hosseinikhahmanshadi
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Ophthalmology
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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
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Demographic information and research results

When the data will become available and for how long
After submitting the final report. Early in the year 2020

To whom data/document is available
It will be available to researchers working in academic and scientific institutions.

Under which criteria data/document could be used
In compliance with copyright laws

From where data/document is obtainable
Call the number and email

What processes are involved for a request to access data/document
After submitting the request and reviewing it, they will be answered as soon as possible. (1 week)

Comments