Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

Comparative study of the effect of oral prednisolone on postoperative tonsillectomy pain in adults

Protocol summary

Study aim
Determining and comparing the effect of oral prednisolone on pain after tonsillectomy with suture in adults
Design
A clinical trial with a control group, with a parallel group, three blinded, randomized, phase 3 on 60 patients, random numbers are used for randomization.
Settings and conduct
This study is carried out in Kashani and Al-Zahra Hospital, Isfahan. The patient, drug delivery and analyzer are blinded. Patients are selected from tonsil surgery candidates and after obtaining informed consent, patients are divided into two groups. The intervention group and the control group are examined for one week in terms of post-operative pain level.
Participants/Inclusion and exclusion criteria
Inclusion criteria Tonsil stone Chronic tonsil infection Suspicion of tonsil tumor Nocturnal snoring requires tonsillectomy Non-entry criteria Diabetes High blood pressure Corticosteroid drug use Taking immunosuppressive drugs
Intervention groups
In the intervention group, for one week, patients are treated with a 0.5 mg/kg prednisolone tablet and one 500 mg acetaminophen tablet every 6 hours. In the control group, patients take placebo and one 500 mg acetaminophen tablet with the above prescription (similar to the other group).
Main outcome variables
Post-operative pain

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20230709058726N1**
Registration date: **2023-07-29, 1402/05/07**
Registration timing: **registered_while_recruiting**

Last update: **2023-07-29, 1402/05/07**
Update count: **0**
Registration date
2023-07-29, 1402/05/07

Registrant information
Name
nezamodin berjis
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 939 991 6574
Email address
berjis@med.mui.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-07-23, 1402/05/01
Expected recruitment end date
2024-06-21, 1403/04/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparative study of the effect of oral prednisolone on postoperative tonsillectomy pain in adults

Public title
Investigating the effect of prednisolone on the pain after tonsillectomy
Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having tonsil stones or chronic tonsil infection or tonsil tumor or nocturnal snoring requires tonsillectomy Consent to participate in the study

Exclusion criteria:

Having diabetes Having hypertension Using corticosteroids Using immunosuppressives

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

After the patients meet the criteria of entering the study, their group will be determined by the random code that is given to them.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Each patient received him/her drugs by showing the code to a pharmacist, who was blind to codes and only gave the sealed drug pocket assigned to each code, containing prednisolone tab or placebo, to the patient. The placebo tab was designed precisely as the prednisolone tab and contained starch. Control group patients receive as many placebo tabs as if it was prednisolone.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Medical School Isfahan University of Medical Sciences

Street address

Hezar Jerib

City

Isfahan

Province

Isfehan

Postal code

8176664348

Approval date

2020-11-15, 1399/08/25

Ethics committee reference number

IR.MUI.MED.REC.1399.715

Health conditions studied

1

Description of health condition studied

Post-tonsillectomy pain

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Post-operative pain

Timepoint

Daily for a week

Method of measurement

A Visual Analog Scale (VAS) is a measurement tool used to assess subjective experiences, such as pain. It typically consists of a straight line with endpoints representing the extremes of the experience being measured, and the participant is asked to mark their level of experience on the line.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group, patients are treated with 0.5 mg/kg prednisolone and one 500 mg acetaminophen tablet every 6 hours for one week.

Category

Treatment - Drugs

2

Description

Control group: In the control group, patients take placebo + one 500 mg acetaminophen tablet with the above instructions (similar to the other group). Placebo looks similar to prednisolone tablets and contains starch. The placebo is produced in Isfahan Faculty of Pharmacy of Medical Sciences.

Category

Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Kashani Hospital
Full name of responsible person
Amin Shayan
Street address
kashani St.
City
Isfahan
Province
Isfehan
Postal code
8179997653
Phone
+98 31 3233 0091
Email
amin.shayan068@gmail.com

2

Recruitment center
Name of recruitment center
Alzahra Hospital
Full name of responsible person
Amin Shayan
Street address
soffeh St.
City
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Province
Isfehan
Postal code
8176661854
Phone
+98 31 3792 2000
Email
amin.shayan068@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Gholamreza Askari
Street address
Hezar jerib ave
City
Isfahan
Province
Isfehan
Postal code
8179994523
Phone
+98 31 3792 3060
Email
askari@mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Nezamodin Berjis
Position
Professor
Latest degree
Specialist
Other areas of specialty/work
Ear, Nose, and Throat
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Person responsible for scientific inquiries

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Position
Professor
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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
Nezamodin Berjis

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Email
berjis@med.mui.ac.ir

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
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
Data and their analysis in an unidentifiable manner

When the data will become available and for how long
The access period starts 6 months after the results are published

To whom data/document is available
Researchers

Under which criteria data/document could be used
Further analysis can be done with coordination and permission.

From where data/document is obtainable
Dr. Amin Shayan, by sending an email to amin.shayan068@gmail.com

What processes are involved for a request to access data/document
The requester will be answered within one working week after sending the email

Comments