Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Jun 2026

Evaluation of the effect of preemptive intravenous dexamethasone on post-tonsillectomy pain, a randomized triple blind study.

Protocol summary

Summary

Objectives: evaluation of the effect of preemptive intravenous dexamethasone on post-tonsillectomy pain. Design: a randomized triple blind study. Setting and conduct: evaluation of pain 1, 4, 10, and 24 hours after surgery with Faces Pain Scale Questionnaire. Major inclusion criteria: all patients with chronic tonsillitis (with or without caseum) with obstructive symptoms; without response to medical therapy who are candidate for adenotonsillectomy. Major exclusion criteria: allergy to dexamethasone; coagulative disorders; non cooperative patients (cerebral palsy,...) or parents; post op bleeding that needs control in OR. Intervention: 1) Intervention group: Iv dexamethasone (Alborz daru Co.) 0.1 mg/kg 1 hour before surgery. 2) Control group: IV distilled water 1 hour before surgery. main outcome measures (variables): evaluation of post tonsillectomy pain at first post op 24 hours.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015112024852N2**
Registration date: **2016-08-28, 1395/06/07**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-08-28, 1395/06/07

Registrant information

Name

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Name of organization / entity

Hamedan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Hamedan university of medical sciences.

Expected recruitment start date

2015-12-31, 1394/10/10

Expected recruitment end date

2016-06-30, 1395/04/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of preemptive intravenous dexamethasone on post-tonsillectomy pain, a randomized triple blind study.

Public title

Reduction of post tonsillectomy pain.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: all patients with chronic tonsillitis (with or without caseum) with obstructive symptoms; without response to medical therapy who are candidate for adenotonsillectomy. Exclusion criteria: allergy to dexamethasone; coagulative disorders; non cooperative patients (cerebral palsy,...) or parents; post op bleeding that needs control in OR.

Age

From **5 years** old to **15 years** old

Gender
Both

Phase
4
Groups that have been masked
No information
Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Triple blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features
randomization: block randomization

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Hamedan university of medical sciences
Street address
Shahid Fahmideh avenue, Hamedan
City
Hamedan
Postal code
Approval date
2015-10-17, 1394/07/25
Ethics committee reference number
IR.UMSHA.REC.1394.328

Health conditions studied

1

Description of health condition studied
post tonsillectomy pain
ICD-10 code
J35.0, J35
ICD-10 code description
Chronic tonsillitis, Hypertrophy of tonsils with hypertrophy of adenoids.

Primary outcomes

1

Description
Evaluation of post tonsillectomy pain at first post op 24 hours.
Timepoint
1, 4, 10, and 24 hours after surgery.
Method of measurement
Faces Pain Scale questionnaire

Secondary outcomes

1

Description
Times of nausea and vomiting
Timepoint
1, 4, 10, 24 hours after adenotonsillectomy
Method of measurement
Questionnaire

2

Description
Time of first feeding
Timepoint
Time of first feeding
Method of measurement
Questionnaire

3

Description
Times of analgesic consumption.
Timepoint
1, 4, 10, 24 hours after adenotonsillectomy
Method of measurement
Questionnaire

Intervention groups

1

Description
Intervention:Iv dexamethasone (Alborz daru Co.) 0.1 mg/kg 1 hour before surgery.
Category
Treatment - Drugs

2

Description
Control:IV distilled water 1 hour before surgery.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Besat hospital
Full name of responsible person
Dr Ruhollah Abbasi
Street address

City
Hamedan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Hamedan university of medical sciences
Full name of responsible person
Dr. Saeed Bashirian
Street address
Shahid Fahmideh avenue, Hamedan
City
Hamedan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Hamedan university of medical sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
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Assistant professor of ENT and head and neck surgery
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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty