

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

16 Sep 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

Ruhollah Abbasi

##### Name of organization / entity

Hamedan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 81 3252 0182

##### Email address

r.abbasi@umsha.ac.ir

##### 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:lv 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**

Hamedan university of medical sciences

**Full name of responsible person**

Ruhollah Abbasi

**Position**

Assistant professor of ENT and head and neck surgery

**Other areas of specialty/work**

**Street address**

Shahid Motahari boulevard, Besat hospital

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## Person responsible for scientific

## inquiries

#### Contact

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## Person responsible for updating data

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## 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*