

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Effects Of Dexamethasone On Post-Tonsillectomy complications

Protocol summary

Study aim

The aim of this study is evaluating Dexamethasone effects on post- tonsillectomy complications in patients , which if it is effective, it can be used routinely.

Design

Controlled clinical trial with parallel groups, double blinded, randomized with table of random numbers

Settings and conduct

In this study, 50 patients candidate for tonsillectomy presenting to Qods teaching hospital, receive 0/15mg/kg IV Dexamethasone at discharging and day 5 after surgery in intervention group and same dose of normal Salin only at discharging, and in 5th and 10th days after surgery, pain ,nausea, vomiting and hemorrhage of both groups assessed. Patients and data analyzer don't inform about their groups and we specialize code to each group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients living in Qazvin city loss of coagulopathies or Diabetes mellitus no consumption of corticosteroids or anti- emetic agents Exclusion criteria:coagulopathies or Diabetes mellitus consumption of corticosteroids or anti- emetic agents

Intervention groups

In intervention group, we inject 0.15 mg/kg Dexamethasone IV, in time of discharging and 5 days after surgery.

Main outcome variables

nausea, vomiting, hemorrhage, paing

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190112042334N1**

Registration date: **2019-02-09, 1397/11/20**

Registration timing: **retrospective**

Last update: **2019-02-09, 1397/11/20**

Update count: **0**

Registration date

2019-02-09, 1397/11/20

Registrant information

Name

Soheyla Faraji

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-19, 1397/11/30

Expected recruitment end date

2019-04-19, 1398/01/30

Actual recruitment start date

2018-10-11, 1397/07/19

Actual recruitment end date

2018-12-30, 1397/10/09

Trial completion date

2019-01-09, 1397/10/19

Scientific title

Effects Of Dexamethasone On Post-Tonsillectomy complications

Public title

Effects Of Corticosteroids On Tonsil Surgery Complications

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

patients living in Qazvin city Loss of Diabetes mellitus or coagulopathies No consumption of Corticosteroids or Anti-emetic agents

Exclusion criteria:
Coagulopathies or Diabetes mellitus Consumption of
Corticosteroids or anti- emetic agents

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **50**
Actual sample size reached: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
Random allocation was done to the study groups.
Randomized random numbers were used to randomized.

Blinding (investigator's opinion)
Double blinded

Blinding description
Data analyzer and patients don't know how we intervene
and they are in which group. Code was defined for study
groups.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Qazvin University of Medical
Sciences

Street address

Mavadat alley, Shahid Beheshti Blvd, Qazvin

City

Qazvin

Province

Qazvin

Postal code

13911/34156

Approval date

2017-10-16, 1396/07/24

Ethics committee reference number

IR.QUMS.REC.1396.279

Health conditions studied

1

Description of health condition studied

Post- Tonsillectomy complications

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Determination of pain score by VAS scale and rate of
nausea, vomiting and hemorrhage

Timepoint

5th day after tonsillectomy

Method of measurement

visual analogue scale to determine pain score and asking
patient about having or not nausea, vomiting and
hemorrhage

Secondary outcomes

1

Description

Determination of pain score by VAS scale and rate of
nausea, vomiting and hemorrhage

Timepoint

10th day after tonsillectomy

Method of measurement

Using visual analogue scale to determine pain score and
asking patient about having or not nausea, vomiting and
hemorrhage

Intervention groups

1

Description

Intervention group: 0/15 mg/kg Dexamethason injected
for patients intravenously when they discharged and at
day 5 after surgery

Category

Treatment - Drugs

2

Description

Control group: 0/15mg/kg normal Saline injected for
these patients when they discharged and they receive no
medication at day 5 after surgery.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Qods teaching hospital

Full name of responsible person

Soheyla Faraji

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Qazvin University of Medical Sciences

Full name of responsible person

Dr. Amir Peymani

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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

Qazvin 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**

Qazvin University of Medical Sciences

Full name of responsible person

Soheyla Faraji

Position

Medical student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

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Latest degree

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Person responsible for updating data**Contact****Name of organization / entity**

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to

make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to
make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to
make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to
make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to
make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to
make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to
make this available