

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

Determination of Dexamethasone Effects on Postoperative Pain, Nausea and Vomiting, Bleeding, Odynophagia, Voice change, Halitosis, Otagia after Tonsillectomy in Children Aged 4 to 10 Years

Protocol summary

2015-09-09, 1394/06/18

Summary

Aim of the study: Determination the effect of dexamethasone on postoperative pain, nausea and vomiting, bleeding, odynophagia, voice change, halitosis, otalgia after tonsillectomy in children Key Inclusion Criteria: 4 to 10 years old candidate patients for tonsillectomy Key Exclusion Criteria: Children were excluded if they had a history of convulsion, prematurity, allergy or hypersensitivity to dexamethasone, syndromic disease (e.g. Down syndrome), coagulation disorder, systemic disease, developmental problems, congenital heart disease, nutritional deficiencies like SDP, G6PD and patient with poor follow up. Study Population: One hundred candidate patients aged 4 to 10 years for adenotonsillectomy surgery. Random division: 50 patients in interventional group, 50 patients in control group. Study Intervention: In interventional group: using dexamethasone 0.1 mg/kg after adenotonsillectomy (in ward), in control group: using ringer serum after adenotonsillectomy (in ward) Primary outcome: Evaluation of bleeding, nausea and vomiting, odynophagia, voice change 1 day and during 7 days after surgery and evaluation of acetaminophen intake, halitosis and otalgia during 7 days after surgery by physical examination and questionnaires

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015080522889N2**
Registration date: **2015-09-09, 1394/06/18**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

Registrant information

Name

Saeid Pourseirafi

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 913 681 2273

Email address

pourseirafi@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2011-12-21, 1390/09/30

Expected recruitment end date

2013-02-18, 1391/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Determination of Dexamethasone Effects on Postoperative Pain, Nausea and Vomiting, Bleeding, Odynophagia, Voice change, Halitosis, Otagia after Tonsillectomy in Children Aged 4 to 10 Years

Public title

Advantages and Disadvantages of Dexamethasone Administration after Tonsillectomy in Children

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: 4 to 10 years old children candidate for adenotonsilectomy in Khalili hospital between February 2011 and March 2013; Completing consent form; Completing demographic information and questionnaire
Exclusion criteria: Patient's with history of convulsion; prematurity; allergy or hypersensitivity to dexamethasone; syndromic disease (e.g. Down syndrome) ; coagulation disorder; systemic disease; developmental problems; congenital heart disease; nutritional deficiencies like SDP and G6PD; patient with poor follow up.

Age

From **4 years** old to **10 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shiraz University of Medical Sciences

Street address

Medical college, Imam Hossein square, Zand street, Shiraz

City

Shiraz

Postal code

7134845794

Approval date

2015-08-19, 1394/05/28

Ethics committee reference number

ir.sums.rec.1394.100

Health conditions studied

1

Description of health condition studied

Hypertrophy of tonsils and adenoids

ICD-10 code

J35.8

ICD-10 code description

Hypertrophy of tonsils with hypertrophy of adenoids

Primary outcomes

1

Description

bleeding

Timepoint

1 day and during 7 days after surgery

Method of measurement

physical examination and questionnaire

2

Description

nausea and vomiting

Timepoint

1 day and during 7 days after surgery

Method of measurement

physical examination and questionnaire

3

Description

odynophagia

Timepoint

1 day and during 7 days after surgery

Method of measurement

physical examination and questionnaire

4

Description

voice change

Timepoint

1 day and during 7 days after surgery

Method of measurement

physical examination and questionnaire

5

Description

acetaminophen intake

Timepoint

during 7 days after surgery

Method of measurement

physical examination and questionnaire

6

Description

halitosis

Timepoint

during 7 days after surgery

Method of measurement

physical examination and questionnaire

7

Description

otalgia

Timepoint

during 7 days after surgery

Method of measurement

physical examination and questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

In interventional group: using dexamethasone 0.1 mg/kg after adenotonsilectomy (in ward)

Category

Treatment - Drugs

2

Description

In control group: using ringer serum after adenotonsilectomy (in ward)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Khalili Hospital

Full name of responsible person

Dr.Saeid Pourseirafi

Street address

Khalili hospital, Khalili street, Shiraz

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr.Reza Kaboodkhani

Street address

Medical College, Imam Hossein square, Zand street,
Shiraz

City

Shiraz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Dr.Saeid Pourseirafi

Position

ENT resident

Other areas of specialty/work

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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