

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 2026

Effect of local sucralfate and clindamycin on reduction of post tonsillectomy pain in 6-12 years children: a triple blinded randomized controlled trial

Protocol summary

Summary

Objective: To assess the effect of local sucralfate and clindamycin on reduction of post tonsillectomy pain in 4-12 years children. Design: A triple blinded randomized controlled trial. Setting: The eligible patients who were undergone tonsillectomy with or without adenoidectomy will refer to ENT clinic of Besat hospital in 2013. Inclusion criteria: (a) patients who were undergone tonsillectomy with or without adenoidectomy; (b) age of 6-12 years of both genders. Exclusion criteria: (a) sensitivity to sucralfate and clindamycin or any of the macrolide antibiotics; (b) having chronic diseases such as congenital malformation, haemorrhagic disease, and Type I diabetes. Intervention 1: oral irrigation with 10 ml of normal saline including clindamycin with 3 gr per 120 ml concentration for one min, immediately before and after surgery and then 3-time a day for three days. Intervention 2: oral irrigation with 10 ml of normal saline including sucralfate with 3 gr per 120 ml concentration for one min, immediately before and after surgery and then 3-time a day for three days. Control: oral irrigation with 10 ml of normal saline including cellulose (as placebo) with 3 gr per 120 ml concentration for one min, immediately before and after surgery and then 3-time a day for three days. Primary outcome: measuring daily sore throat for five days using Faces Pain Scale Revised with 0-10 scores. Secondary outcome: assessing adverse events during the first 5 days after surgery including: (a) nausea; (b) vomiting; (c) bleeding; (d) number of times of using acetaminophen; (e) number of times awaking at night; (f) bad breath; and (g) Otagia

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201303209014N16**

Registration date: **2013-04-21, 1392/02/01**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-04-21, 1392/02/01

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan
University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor of Research the Technology, Hamadan
University of Medical Sciences

Expected recruitment start date

2013-04-21, 1392/02/01

Expected recruitment end date

2014-04-20, 1393/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of local sucralfate and clindamycin on reduction of post tonsillectomy pain in 6-12 years children: a triple blinded randomized controlled trial

D-3-16-35-9-4026

Public title

Effect of local sucralfate and clindamycin on reduction of post tonsillectomy pain in 4-12 years children

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: (a) patients who were undergone tonsillectomy with or without adenoidectomy; (b) age of 4-12 years of both genders. Exclusion criteria: (a) sensitivity to sucralfate and clindamycin or any of the macrolide antibiotics; (b) having chronic diseases such as congenital malformation, haemorrhagic disease, and Type I diabetes.

Age

From **6 years** old to **12 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **105**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor of Research the Technology,
Hamadan University of Medical Sciences, Shahid
Fahmideh Ave.

City

Hamadan

Postal code

6517838695

Approval date

2013-02-14, 1391/11/26

Ethics committee reference number

Health conditions studied

1

Description of health condition studied

Sore throat

ICD-10 code

R07.0

ICD-10 code description

Pain in throat

Primary outcomes

1

Description

Measuring daily sore throat for five days giving 0-10 scores.

Timepoint

During 5 days after surgery

Method of measurement

Faces Pain Scale Revised

Secondary outcomes

1

Description

Nausea

Timepoint

During the first 5 days after surgery

Method of measurement

Questionnaire

2

Description

Vomiting

Timepoint

During the first 5 days after surgery

Method of measurement

Questionnaire

3

Description

Bleeding

Timepoint

During the first 5 days after surgery

Method of measurement

Questionnaire

4

Description

Number of times of using acetaminophen

Timepoint

During the first 5 days after surgery

Method of measurement

Questionnaire

5

Description

Number of times awaking at night

Timepoint

During the first 5 days after surgery

Method of measurement

Questionnaire

6

Description

Bad breath

Timepoint

During the first 5 days after surgery

Method of measurement

Questionnaire

7

Description

Otalgia

Timepoint

During the first 5 days after surgery

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention 1: Oral irrigation with 10 ml of normal saline including clindamycin with 3 gr per 120 ml concentration for one min, immediately before and after surgery and then 3-time a day for three days.

Category

Treatment - Drugs

2

Description

Intervention 2: Oral irrigation with 10 ml of normal saline including sucralfate with 3 gr per 120 ml concentration for one min, immediately before and after surgery and then 3-time a day for three days.

Category

Treatment - Drugs

3

Description

Control: Oral irrigation with 10 ml of normal saline including cellulose (as placebo) with 3 gr per 120 ml concentration for one min, immediately before and after surgery and then 3-time a day for three days

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat hospital

Full name of responsible person

Dr Javaneh Jahanshahi

Street address

Besat Hospital, Imam Hossein Square

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for Research the Technology, Hamadan University of Medical Sciences

Full name of responsible person

Dr Heidar Tavilani

Street address

Vice chancellor for Research the Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave,

City

Hamadan

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 the Technology, Hamadan 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

Besat Hospital

Full name of responsible person

Dr Sara Pazira

Position

Resident of ENT

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Besat Hospital
Full name of responsible person
Dr Javaneh Jahanshahi
Position
Specialist in ENT
Other areas of specialty/work
Street address
Besat Hospital, Imam Hossein Square
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Postal code
Phone

Person responsible for updating data

Contact

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