Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 plaocebo) 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) Otalgia

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

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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

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
D-3-16-35-9-4026

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 plaocebo) 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
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Resident of ENT
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Person responsible for scientific inquiries

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Web page address

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