

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 2026

A comparative study of honey and Diphenhydramine for control post tonsillectomy pain in children

Protocol summary

Summary

The goal of study was comparing effect of honey and diphenhydramine on post tonsillectomy pain. This study did double blind clinical trial. 120 children 5-12 who candidated for tonsillectomy studied. main exclusion criteria were dissatisfaction of cooperation, sensitivity to honey, inability to count number 1-5, lack of swallowing reflex. Patients divided randomly to four equal groups, after tonsillectomy first group received pure honey 5cc a one hour depended on wished child, second group received 50% honey 5cc a one hour depended on wished child, third group received diphenhydramine 1mg/kg every six hour, fourth group follow up without intervention. All groups received acetaminophen 10mg/kg every six hour. The intensity of pain was evaluated in 0,3,6,12,24 hours after tonsillectomy by Oucher questioner

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201207086252N3**

Registration date: **2012-08-31, 1391/06/10**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-08-31, 1391/06/10

Registrant information

Name

Soroush Amani

Name of organization / entity

Shahrekord University of Medical Sciences

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Iran (Islamic Republic of)

Phone

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samani@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahrekord University of Medical Sciences

Expected recruitment start date

2007-03-20, 1385/12/29

Expected recruitment end date

2009-03-20, 1387/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study of honey and Diphenhydramine for control post tonsillectomy pain in children

Public title

effect of honey on pain after tonsillectomy

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: children between 5-12 years undergoing tonsillectomy exclusion criteria: children between 5-12 undergoing tonsillectomy who were dissatisfied of cooperation; children between 5-12 undergoing tonsillectomy who had sensitivity to honey; children between 5-12 undergoing tonsillectomy who could not count numbers 1-5, and lack of swallowing reflex

Age

From **5 years** old to **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 120

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahrekord University of Medical Science

Street address

Ayatolah Kashani Avenue

City

Shahrekord

Postal code

8815713471

Approval date

2006-10-23, 1385/08/01

Ethics committee reference number

85-7-3

Health conditions studied

1

Description of health condition studied

Tonsillar Hypertrophy

ICD-10 code

R07.0

ICD-10 code description

Pain in Throat

Primary outcomes

1

Description

Pain

Timepoint

0-3-6-12,24 hours after tonsillectomy

Method of measurement

Oucher Questionnaire

Secondary outcomes

1

Description

Hemorrhage

Timepoint

24 hours after surgery

Method of measurement

Visual

2

Description

Nausea and Vomiting

Timepoint

24 hours after surgery

Method of measurement

Visual

Intervention groups

1

Description

Third group was treated with 1mg/kg diphenhydramine every 6 hours, after surgery

Category

Treatment - Drugs

2

Description

First group after tonsillectomy and beginning of eating took 5cc pure honey every an hour

Category

Treatment - Drugs

3

Description

Second group after tonsillectomy and beginning of eating took 5cc, 50% honey every an hour

Category

Treatment - Drugs

4

Description

Forth group was observed without any intervention

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatolah kashani Hospital

Full name of responsible person

Soroush Amani MD

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Ayatollah kashani Hospital, Shariati Avenue
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahrekord University of Medical Sciences
Full name of responsible person
Dr Mahmood Mobasheri
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Shahrekord University of Medical Sciences, Kashani Avenue
City
Shahrekord

Grant name

بودجه تحقیقات دانشگاه

Grant code / Reference number

410

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

Yes

Title of funding source

Shahrekord 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
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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