

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

The comparison of the effect of Dextromethorphan with Placebo on postoperative pain in adenotonsillectomy

Protocol summary

Summary

The objective of this randomized clinical trial is to investigate the effect of analgesic efficacy of 0.5mg/kg oral dextromethorphan on postoperative pain in adenotonsillectomy compared with placebo. In this study, 160 children 3-12 years old undergoing surgery for adenotonsillectomy who meet the inclusion/exclusion criteria will be recruited and randomly assigned into intervention or control to four (A,B,C,D) equal groups (40 patients). Two hours before anesthesia, groups A&B will receive 0.5mg/kg oral syrup of dextromethorphan and groups C&D will receive placebo. After operation, groups A&C will receive 0.5mg/kg oral syrup dextromethorphan and groups B&D will receive placebo (in 24 hour). The pain intensity will be evaluated every 6 hours (during the first 24 hour postoperative) by Oucher test.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201104226252N1**

Registration date: **2011-06-30, 1390/04/09**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-06-30, 1390/04/09

Registrant information

Name

Soroush Amani

Name of organization / entity

Shahrekord University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 38 1226 4834

Email address

samani@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellery for Research, Shahrekord University of Medical Sciences.

Expected recruitment start date

2011-06-14, 1390/03/24

Expected recruitment end date

2012-01-20, 1390/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of the effect of Dextromethorphan with Placebo on postoperative pain in adenotonsillectomy

Public title

The comparison of the effect of Dextromethorphan with Placebo on postoperative pain in adenotonsillectomy

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: children with 3-12 years old, undergoing surgery for adenotonsillectomy, not having background on bloodshed disease, non addicted parents, not using walnuts and nuts in 10 recent days, not being prohibited from public operation, not having allergy to drugs Exclusion criteria: severe bloodshed during operation, operation takes time more than 30 min, Laryngospasm during extubation, need to a second operation, bloodshed of the operation area after operation, post operation breathing problem

Age

From **3 years** old to **12 years** old

Gender

Both

Phase

0

Groups that have been masked

No information

Sample size

Target sample size: **160**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Vice chansellor for research, Shahrekord University of Medical Sciences

Street address

Vice chancellor for research, Central Building of Shahrekord University of Medical Sciences, Kashani Avenue

City

Shahrekord

Postal code

Approval date

2005-04-21, 1384/02/01

Ethics committee reference number

84-2-5

Health conditions studied

1

Description of health condition studied

Intensity of Pain

ICD-10 code

R46

ICD-10 code description

Symptoms and signs involving appearance and behaviour

Primary outcomes

1

Description

pain intensity

Timepoint

before and after interval

Method of measurement

visual scale af pain

Secondary outcomes

empty

Intervention groups

1

Description

5ml of decstrometorphan 2 h before and after operation every 6 h till 24h

Category

Treatment - Drugs

2

Description

Placebo 2h before and after operation every 6h till 24h

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Kashani Hospital

Full name of responsible person

Dr Hossein Madineh

Street address

Anaesthesiology department, Hajar hospital, Parastar St.

City

Shahrekord

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahrekord University of Medical Sciences, Vice chancellor for research

Full name of responsible person

Mahmoud Mobasheri

Street address

Shahrekord University of Medical Science, Kashani St.

City

Shahrekord

Grant name

Grant code / Reference number

Is the source of funding the same sponsor

organization/entity?

Yes

Title of funding source

Shahrekord University of Medical Sciences, Vice
chancellory for research

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**

Shahrekord University of Medical Science

Full name of responsible person

Hossein Madineh

Position

Assistant professor ,Anesthesiology department

Other areas of specialty/work**Street address**

Anesthesiology department, Hajar hospital, Parastar
ST.

City

Shahrekord

Postal code**Phone**

+98 38 1222 0016

Fax**Email**

hosseinmadineh@gmail.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shahrekord University of Medical Sciences

Full name of responsible person

Dr Hossein Madineh

Position

Assistant professor, Anaesthesiology departmet

Other areas of specialty/work**Street address**

Anaesthesiology department, Hajar hospital, Parastar
St.

City

Shahrekord

Postal code**Phone**

+98 38 1222 0016

Fax**Email**

hosseinmadineh@gmail.com

Web page address

WWW.skums.ac.ir

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

Shahrekord University of Medical Science

Full name of responsible person

Soroush Amani

Position

Assistant professor, ENT department

Other areas of specialty/work**Street address**

ENT dept, Kashani hospital, Parastar St.

City

Shahrekord

Postal code**Phone****Fax****Email**

soamani2008@yahoo.com

Web page address**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