Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Jun 2026

Study of the efficacy of Turmeric oil oral spray (Curcumin) on reduction of post Adenotonsillectomy pain in 4-12 years old children: three blind randomized clinical trial

Protocol summary

Study aim
Finding an Effective, Lowly-Effective, and Cheap Drug to Reduce Pain In Candidates for Adenotonsillectomy

Design
Triple blind randomized trials with 122 patients

Settings and conduct
Patients undergoing adenotonsillectomy surgery who have been admitted to the ENT clinic since the approval of this plan for one year, will be included in the study if they are eligible for entry and consent. Blind Mode: Due to the type of intervention and coding, patients, researchers, and analyst do not know the contents of the spray used.

Participants/Inclusion and exclusion criteria
Entry requirements: Children aged 4 to 12 years old from both sexes candidates for adenotonsillectomy Conditions of absence: Sensitivity to Turmeric, use of cautery in surgery, any systemic illness, lack of understanding of the child from the visual scale of pain, lack of consent of the child's parents

Intervention groups
Intervention group: The surgical site is rinsed, then use a Turmeric spray spray at 2 puffs one minute before surgery and use the same amount of spray immediately after surgery, then use spray once a day 3 times and 2 times Buff, for 5 days Control group: The surgical sitewas rinsed, then using normal saline spray at 2 minutes before surgery and using the same spray immediately after surgery, then using spray once a day, 3 times each time. 2 puffs, for 5 days

Main outcome variables
Scale of sore throat in the Visual Analog Scale (VAS) Questionnaire in the first 5 days after adenotonsillectomy

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130713013976N6**
Registration date: **2018-12-05, 1397/09/14**
Registration timing: **registered_while_recruiting**

Last update: **2018-12-05, 1397/09/14**
Update count: **0**

Registration date
2018-12-05, 1397/09/14

Registrant information

Name
Javaneh Jahanshahi

Name of organization / entity
Hamedan University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-10-23, 1397/08/01

Expected recruitment end date
2019-04-21, 1398/02/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Study of the efficacy of Turmeric oil oral spray (Curcumin) on reduction of post Adenotonsillectomy pain in 4-12 years old children: three blind randomized clinical trial

Public title
Effect of Curcumin in Adenotonsillectomy pain reduction

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients undergoing Adenotonsillectomy Age 4 to 12 years of both sexes

Exclusion criteria:
Sensitivity to Turmeric Using cautery during surgery In the absence of understanding the pain assessment images by the child and the inability to intervene and lack of parental support Any known systemic disease, such as congenital anomalies, bleeding disorders, type 1 diabetes, kidney disease, colds, and fever

Age
From **4 years** old to **12 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **122**

Randomization (investigator's opinion)
Randomized

Randomization description
For this purpose, we will use the Block Randomization block method. In this method, we prepare four paper sheets. On the two letters "C" means "Curcuma Longa" (intervention group) and we write two letters of the letter "N" meaning "Normal Saline" (control group). We mix the sheets together. Then, by random selection of the sheets, the Turmeric and Normal Saline spray from one to one hundred and twenty will be numbered respectively. The drug code will be covered by researchers until the end of the study. By referring to each patient, we choose one of the vials randomly and deliver it to the patient. The scientist who will deliver the medication to the patient and the patient interviewer will not be aware of the type of medication used. Then, the data collected by the C, N codes (these codes refer to Turmeric spray and Normal Saline, and the analyzer does not know how to assign the codes to the drugs), will enter the statistical software version 16 and will be analyzed. After the data is analyzed and the results are finalized, the drug code is decoded and the effect of each drug will be identified and recorded.

Blinding (investigator's opinion)
Triple blinded

Blinding description
In this study, the shape of both sprays (Curcumin and placebo) was identical and randomly Quadrupled randomized blocks were randomly assigned. Spray distributors (researchers) and patients and the person who performs statistical analysis do not know the nature of the substance in the spray. After analyzing the data and identifying the results, the drug code is decoded and the effect of each drug will be identified and recorded. Therefore, this study is done in a three blind randomized clinical trial.

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 Science

Street address
Ethics Committee of Hamadan University of Medical Science, Khaje Rashid Blv., Hamadan, Iran

City
Hamadan

Province
Hamadan

Postal code
1234567890

Approval date
2018-09-22, 1397/06/31

Ethics committee reference number
IR.UMSHA.REC.1397.440

Health conditions studied

1

Description of health condition studied
Adenotonsillar hypertrophy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Scale of sore throat in the Visual Analog Scale (VAS)

Timepoint
Measurement of sore throat in the first 5 days after

Adenotonsillectomy

Method of measurement

Visual Analogue Scale

Secondary outcomes

1

Description

The frequency of use of prescribed acetaminophen intake

Timepoint

In the first 5 days after Adenotonsillectomy

Method of measurement

Questionnaire

2

Description

Having or not having ear pain (autoelastic)

Timepoint

In the first 5 days after Adenotonsillectomy

Method of measurement

Questionnaire

3

Description

Tolerate normal diet

Timepoint

In the first 5 days after Adenotonsillectomy

Method of measurement

Questionnaire

4

Description

Having or not having nausea

Timepoint

In the first 5 days after Adenotonsillectomy

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention group: The surgical site is rinsed, then use aTurmeric spray spray at 2 puffs one minute before surgery and use the same amount of spray immediately after surgery, then use spray once a day 3 times and 2 times

Category

Treatment - Drugs

2

Description

Control group: The surgical site is rinsed, then using normal saline spray at 2 minutes before surgery and using the same spray as immediately after surgery, then using spray 3 times a day, 2 puffs per day, For 5 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

ENT department of BESAT hospital

Full name of responsible person

Dr Javaneh Jahanshahi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Hamedan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
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Medical Student
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All of personal information and data could be shared
When the data will become available and for how long
Access starts from 6 months after results publishing
To whom data/document is available
Researchers
Under which criteria data/document could be used
Just for more researches in this field
From where data/document is obtainable
Nasser Bahari , num ; 00989398225654
What processes are involved for a request to access data/document
Written request and letter of introduction from the subsidiary
Comments