

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### Study of the efficacy of aloe vera mouthwash on reduction of post Adenotonsillectomy pain in 5-12 years old children referred to Behesht Hospital of Hamedan in 2019 : three blind randomized clinical trial

#### Protocol summary

##### Study aim

The efficacy of aloe vera mouthwash on the reduction of post-Adenotonsillectomy pain in 5-12 years old children

##### Design

Interventional and Practical Clinical Trial, Triple-blind, quadruple block randomization, 110 samples in each, intervention and control groups.

##### Settings and conduct

Patients who were candidates for surgery who had been referred to the ENT clinic of Hamadan Besat hospital for one year after the approval of this plan, were included in the study if they were eligible for inclusion and signature of consent. The surgery was performed at 8 to 12 am in Besat hospital. In the surgery room, before the start and after the surgery, surgeon washed the surgical site with the solution for one minute. The following days, patient washed their mouth with the solution 3 times daily and data were noted daily by the researcher using phone call. According to the method of intervention and coding, the patients, researcher, and statistical analyzer were blind.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Children aged 5 to 12 years old; both sexes; candidates for adenotonsillectomy. Exclusion criteria: Sensitivity to aloe vera, use of cautery in surgery, any systemic illness, No understanding of visual scale by child; No consent of the child's parents

##### Intervention groups

Intervention group: The surgical site was washed. Then 10 cc of Aloe vera mouth wash was applied 1 minute before the surgery and the same amount right after surgery. The mouth wash was used 5 ccs 3 times a day for 5 days.

Control group: The surgical site was washed. Then 10 cc of normal saline mouth wash was applied 1 minute before the surgery and the same amount right after surgery. The mouth wash was used 5 ccs 3 times a day 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: **IRCT20130713013976N7**

Registration date: **2019-09-08, 1398/06/17**

Registration timing: **retrospective**

Last update: **2019-09-08, 1398/06/17**

Update count: **0**

##### Registration date

2019-09-08, 1398/06/17

##### Registrant information

##### Name

Javaneh Jahanshahi

##### Name of organization / entity

Hamedan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 81 1264 0020

##### Email address

j.jahanshahi@umsha.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-09-23, 1397/07/01

##### Expected recruitment end date

2019-06-10, 1398/03/20

##### Actual recruitment start date

2018-09-23, 1397/07/01

**Actual recruitment end date**

2019-06-20, 1398/03/30

**Trial completion date**

2019-06-20, 1398/03/30

**Scientific title**

Study of the efficacy of aloe vera mouthwash on reduction of post Adenotonsillectomy pain in 5-12 years old children referred to Behesht Hospital of Hamedan in 2019 : three blind randomized clinical trial

**Public title**

Effect of Aloe vera in Adenotonsillectomy pain reduction

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Patients undergoing Adenotonsillectomy  
Age 4 to 12 years  
Both sexes

**Exclusion criteria:**

Sensitivity to Aloe vera  
Any known systemic disease, such as congenital anomalies, bleeding disorders, type 1 diabetes, kidney disease, colds, and fever  
Using cautery during surgery  
No understanding the pain assessment tool (VAS) by the child;  
No parental consent

**Age**

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

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Care provider
- Investigator
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **220**

Actual sample size reached: **220**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

This activity was performed by a pharmacist colleague. For this purpose, quadratic block randomization was used. Therefore, four sheets of paper were prepared and written on two letters A (for Aloe vera group) and two other letters N (for normal saline). The sheets were mixed together and placed in a drawer. One of the sheets was randomly drawn out and assigned to one of two groups (aloe vera or normal saline) whether the paper was assigned to as A or N and thus each group of normal saline and aloe vera bottles was randomly numbered from one to one hundred and twenty. It should be noted that the extruded sheets were not returned to the drawer until all four sheets were removed, and after all the four sheets were randomly removed, all the sheets were returned to the drawer again and the above operation was carried out for another four bottles until one hundred. And ten cases from each group continued.

**Blinding (investigator's opinion)**

Triple blinded

**Blinding description**

In this study, the shape of both bottles (aloe vera and placebo) was identical and was coded by a randomized four-block method. Bottle distributors (researchers), patients and the person performing the statistical analysis were not aware of the nature of the substance in the bottle, and after completing the data analysis and identifying the results, the drug code was decoded and the affect of each drug was identified and recorded.

**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**

2015-08-16, 1394/05/25

**Ethics committee reference number**

IR.UMSHA.REC.1394.276

**Health conditions studied**

**1**

**Description of health condition studied**

Adenotonsillar hypertrophy

**ICD-10 code**

**ICD-10 code description**

**Primary outcomes**

**1**

**Description**

Sore throat

**Timepoint**

Measurement of sore throat in the first 5 days after Adenotonsillectomy

**Method of measurement**

Visual Analogue Scale (VAS)

## 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

Ear pain (autoelastic)

#### Timepoint

In the first 5 days after Adenotonsillectomy

#### Method of measurement

Questionnaire

### 3

#### Description

Normal diet tolerance

#### Timepoint

In the first 5 days after Adenotonsillectomy

#### Method of measurement

Questionnaire

## Intervention groups

### 1

#### Description

Intervention group: The surgical site was washed. Then 10 cc of Aloe vera mouth wash was applied 1 minute before the surgery and the same amount right after surgery. The mouth wash was used 5 cc 3 times a day for 5 days.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: The surgical site was washed. Then 10 cc of normal saline mouth wash was applied 1 minute before the surgery and the same amount right after surgery. The mouth wash was used 5 cc 3 times a day for 5 days.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

E.N.T department of besat hospital

##### Full name of responsible person

Dr Javaneh Jahanshahi

#### Street address

Besat hospital E.N.T department, Shahid Beheshti Blvd, Hamadan

#### City

Hamedan

#### Province

Hamadan

#### Postal code

32651515

#### Phone

+98 81 3264 0030

#### Email

Besat@umsha.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Hamedan University of Medical Sciences

##### Full name of responsible person

Dr. Saeed Bashirian

##### Street address

Research and technology department, Hamedan university of medical sciences, Shahid fahmideh street

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##### Province

Hamadan

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1234567890

##### Phone

+98 81 3838 0462

##### Email

ICT@umsha.ac.ir

#### Grant name

#### Grant code / Reference number

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

No

#### Title of funding source

Barij Essence Pharmaceutical Company

#### Proportion provided by this source

100

#### Public or private sector

Private

#### Domestic or foreign origin

Domestic

#### Category of foreign source of funding

empty

#### Country of origin

#### Type of organization providing the funding

Industry

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Hamedan University of Medical Sciences

**Full name of responsible person**

Mohamad Hassan Nazemi

**Position**

Medical student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Practitioner

**Street address**University of Medical science, Ayatollah Kashani Blvd,  
Hamadan, Iran.**City**

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

Hamedan University of Medical Sciences

**Full name of responsible person**

Javaneh Jahanshahi

**Position**

Assistant professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Ear, Nose, and Throat

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**Province**

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**Postal code**

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**Phone**

+98 81 3264 0020

**Email**

J.JAHANSHAHI@UMSHA.AC.IR

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

Hamedan University of Medical Sciences

**Full name of responsible person****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**mohamad hassan nazemi, phone number :  
+989216601218**What processes are involved for a request to access data/document**

Written request and letter of introduction from the subsidiary

**Comments**