# 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**

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**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 Adenotonsillectomyک Age 4 to 12 yearsک 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**
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## Sponsors / Funding sources

**1**

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**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**
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## Person responsible for scientific inquiries

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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**
mohamad hassan nazemi, phone numer : +989216601218
**What processes are involved for a request to access data/document**
Written request and letter of introduction from the subsidiary
**Comments**