

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 2026

### Comparison of cold and liquid diet versus routine Iranian dish on post-tonsillectomy morbidity

#### Protocol summary

##### Summary

Aim of the study is comparison of cold and liquid diet versus routine Iranian dish on post-tonsillectomy morbidity. This was a double blind randomized clinical study in a single center (Dastgheib University Hospital Shiraz-Iran). Physician and statistician as assessors were blind. Patients were divided in two groups; control group (100 patients) which recommended on routine post tonsillectomy diet; that is cold and liquid. Intervention group (100 patients), with no diet limitation, can use regular Iranian dish. Inclusion criteria are: 1) age range 3-15 years old; 2) patients who undergo tonsillectomy. Tonsillectomy due to three or more severe recurrent attacks of tonsillitis within each two consecutive years; 3) educated parents at least at the level of high school. Exclusion criteria are: 1) pre operative medical problems such as asthma, diabetes, coagulation disorders, cardiovascular disease, basic metabolic disorder, immune system deficiency and chronic liver or renal disease; 2) Inadequate follow-up and incomplete questionnaires. Primary outcomes are pain and post operative bleeding within 10 days after operation. Pain will be evaluated by Visual Analog Scale by trained parents at home. Post operative bleeding will be confirmed by otolaryngologist.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014012115496N6**

Registration date: **2016-07-21, 1395/04/31**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-07-21, 1395/04/31

#### Registrant information

##### Name

Sareh Roosta

##### Name of organization / entity

Vice Chancellor for Research and Technology, Shiraz University of Medical Sciences

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Iran (Islamic Republic of)

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#### Recruitment status

##### Recruitment complete

#### Funding source

Vice Chancellor for Research, Shiraz University of Medical Sciences

#### Expected recruitment start date

2015-05-22, 1394/03/01

#### Expected recruitment end date

2016-06-19, 1395/03/30

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Comparison of cold and liquid diet versus routine Iranian dish on post-tonsillectomy morbidity

#### Public title

Comparison of cold and liquid diet versus routine Iranian dish on post-tonsillectomy pain and bleeding

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

Inclusion criteria: 1) age range 3-15 years old; 2) patients who undergo tonsillectomy. Tonsillectomy due to three

or more severe recurrent attacks of tonsillitis within each two consecutive years; 3) educated parents at least at the level of high school. Exclusion criteria: 1) pre operative medical problems such as asthma, diabetes, coagulation disorders, cardiovascular disease, basic metabolic disorder, immune system deficiency and chronic liver or renal disease; 2) Inadequate follow-up and incomplete questionnaires.

**Age**

From **3 years** old to **15 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **200**

**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**

Ethics committee of Shiraz University of Medical Sciences

**Street address**

Shiraz University of Medical Sciences, Zand Street, Shiraz

**City**

Shiraz

**Postal code****Approval date**

2016-06-22, 1395/04/02

**Ethics committee reference number**

IR.sums.med.rec.1395.14

**Health conditions studied****1****Description of health condition studied**

Tonsillectomy

**ICD-10 code**

J35.1, J35

**ICD-10 code description**

Hypertrophy of tonsils, Hypertrophy of tonsils with hypertrophy of adenoids

**Primary outcomes****1****Description**

Post-tonsillectomy pain

**Timepoint**

within 10 days after surgery

**Method of measurement**

Visual Analog Scale (VAS)-by trained parents at home

**2****Description**

Post-tonsillectomy bleeding

**Timepoint**

within 10 days after surgery

**Method of measurement**

Observation by ENT specialist

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Control group receives routine cold and liquid post tonsillectomy diet.

**Category**

Prevention

**2****Description**

Intervention group, without diet limitation, can use regular Iranian dish.

**Category**

Prevention

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Shahid Dastgheib Hospital

**Full name of responsible person**

Dr. Mohammad Faramarzi

**Street address**

Hafez Street, Next to National Garden

**City**

Shiraz

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Vice Chancellor for Research, Shiraz University of Medical Sciences

**Full name of responsible person**

Dr. Seyed Basir Hashemi

**Street address**

Shiraz University of Medical Sciences, Zand Street, Shiraz

**City**

Shiraz

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice Chancellor for Research, Shiraz 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**

Center for Development of Clinical Studies, Vice Chancellor of Research and Technology, Shiraz Unive

**Full name of responsible person**

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## Person responsible for scientific

## inquiries

#### Contact

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**Full name of responsible person**

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## Person responsible for updating data

#### Contact

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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*