

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of Pretreatment of oral pentoxifylline administration on post-operative pain and development of hyperalgesia in patient under appendectomy surgery

#### Protocol summary

##### Study aim

The main objective of this study was to evaluate the effect of oral pentoxifylline premedication on postoperative pain and hyperalgesia in patients undergoing appendectomy.

##### Design

Clinical trial study of the control and intervention group, randomized double-blind, randomized groups

##### Settings and conduct

In this study, the independent effect of pentoxifylline administration on postoperative pain, hyperlipidemia, behavioral reactions to pain and appendectomy in patients undergoing appendectomy in a rescue hospital admitted to Sabzevar University of Medical Sciences in 1391-97. In this study, patients and researchers were blinded.

##### Participants/Inclusion and exclusion criteria

The study population will be 90 patients with men and women admitted to the emergency department. Entry requirements include appendectomy surgery, age range of 15-45 years, non-addiction to cigarettes, alcohol and drugs, lack of mental illness or disease, special areas of interest and participation in the study, and exclusion criteria including liver disease, and a history of seizure.

##### Intervention groups

Pentoxifylline group: This group receives a dose of pentoxifylline 10 mg / kg for half an hour before surgery.  
Placebo group: This group receives placebo instead of pentoxifylline half an hour before the placebo.

##### Main outcome variables

Pain level after surgery, Postoperative analgesic drug intake, The interval between the need for analgesic drug intake, Satisfaction rate, The rate of mechanical hyperalgesia around the wound the expression of TNF-alpha

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180522039773N1**

Registration date: **2018-11-24, 1397/09/03**

Registration timing: **retrospective**

Last update: **2018-11-24, 1397/09/03**

Update count: **0**

##### Registration date

2018-11-24, 1397/09/03

##### Registrant information

##### Name

Samad Nazemi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 4401 8368

##### Email address

nazemis@medsab.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-02-20, 1396/12/01

##### Expected recruitment end date

2018-08-06, 1397/05/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

The effect of Pretreatment of oral pentoxifylline administration on post-operative pain and development of hyperalgesia in patient under appendectomy surgery

## Public title

Pretreatment pentoxifylline and control of post operative pain

## Purpose

Basic science

## Inclusion/Exclusion criteria

### Inclusion criteria:

appendectomy surgery Age range 15-45 years Interested in participating in the study

### Exclusion criteria:

Addiction to cigarettes, alcohol and drugs mental illness or a specific disease Sensitivity to Pentoxifylline Liver disease Age over 45 and under 15 years of age

## Age

From **15 years** old to **45 years** old

## Gender

Both

## Phase

0

## Groups that have been masked

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

## Sample size

Target sample size: **90**

Actual sample size reached: **80**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Simple randomization using random numbers table

## Blinding (investigator's opinion)

Double blinded

## Blinding description

Participants, as well as researcher and analyst, do not know the type of intervention performed.

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Sabzevar University of Medical Sciences

##### Street address

Towhid Blvd., Sabzevar University of Medical Sciences, Educational Affairs, Sabzevar, Iran

#### City

Sabzevar

#### Province

Razavi Khorasan

#### Postal code

9613873136

#### Approval date

2016-06-20, 1395/03/31

#### Ethics committee reference number

IR.MEDSAB.REC.1395.47

## Health conditions studied

### 1

#### Description of health condition studied

Postoperative pain

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Pain Scale

#### Timepoint

6- 12-18-24 Hours after surgery

#### Method of measurement

VAS test

### 2

#### Description

Hyperalgesia

#### Timepoint

12-24 Hours after surgery

#### Method of measurement

von Frey test with von frey filaments (180 g)

### 3

#### Description

Ramsay Relaxation Scale

#### Timepoint

12-24 Hours after surgery

#### Method of measurement

Ramsey Relaxation Questionnaire

### 4

#### Description

TNF alpha

#### Timepoint

24 hours after surgery

#### Method of measurement

ELISA

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: A pentoxifylline dose of 10 mg / kg is given orally in half an hour before anesthesia.

#### Category

Treatment - Drugs

### 2

#### Description

Placebo group: One dose of placebo is given orally to patients half an hour before anesthesia.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Vasei Hospital

##### Full name of responsible person

Mahtab Khajeh

##### Street address

Tohid BLvd., Sabzevar

##### City

Sabzevar

##### Province

Razavi Khorasan

##### Postal code

9613873136

##### Phone

+98 51 4465 1300

##### Email

vasei@medsab.ac.ir

##### Web page address

<http://www.medsab.ac.ir/index.aspx?siteid=1&siteid=1&pageid=158>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Sabzevar University of Medical Sciences

##### Full name of responsible person

Samad Nazemi

##### Street address

Sabzevar university of Medical Sciences, Faculty of Medicine, Sabzevar, Iran

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##### Province

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##### Phone

+98 51 4401 8368

##### Email

samadnazemi@gmail.com

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Sabzevar University of Medical Sciences

##### 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

Academic

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Sabzevar University of Medical Sciences

##### Full name of responsible person

Samad Nazemi

##### Position

Assistant professor

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Physiology

##### Street address

University of Medical Sciences, Faculty of Medicine, Department of Physiology, Sabzevar, Iran.

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Sabzevar University of Medical Sciences

##### Full name of responsible person

Samad nazemi

##### Position

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiology

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Medicine, Department of physiology, sabzevar, Iran

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**Person responsible for updating data**

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**Full name of responsible person**

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**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Neuroscience

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**Fax**

**Email**

samadnazemi@gmail.com

**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**

Undecided - It is not yet known if there will be a plan to  
make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to  
make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to  
make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to  
make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to  
make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to  
make this available