Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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)

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+98 51 4401 8368

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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 scienece
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 sergury
Method of measurement
VAS test

2

Description
Hyperalgesia
Timepoint
12-24 Hours after sergury
Method of measurement
von Frey test with von frey filaments (180 g)

3

Description
Ramsay Relaxation Scale
Timepoint
12-24 Hours after sergury
Method of measurement
Ramsey Relaxation Questionnaire

4

Description
TNF alpha
Timepoint
24 hours after sergury
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
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Sponsors / Funding sources

1

Sponsor
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Sabzevar University of Medical Sciences
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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
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
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Position
Assistant professor
Latest degree
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Other areas of specialty/work
Physiology
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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

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