Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of discontinuation of aspirin on complications of inguinal hernia surgery in patients receiving aspirin

Protocol summary

Study aim
The effect of discontinuation of aspirin on complication of inguinal hernia surgery in patient receiving aspirin
Design
Clinical trial with randomized control group. Patients referred to specialized clinics after referral for surgery were randomly divided into two groups.
Settings and conduct
In this study, patients were randomly divided into two groups of 50, based on their inclusion criteria. The first group without aspirin and the second group with aspirin at the Babol University of Medical Sciences affiliated hospitals are going under the hernia repair surgery. The amount of pain is assessed based on the visual scale (VAS) postoperation as well as on possible complications.
Participants/Inclusion and exclusion criteria
Inclusion criteria: Inguinal hernia, age over 18 years old, Daily aspirin therapy Exclusion criteria: Patients with unstable angina, Congestive Heart Failure, Shock, Aspirin sensitivity, History of gastrointestinal and cerebral hemorrhage, Patients treated with Warfarin, plavix and methotrexate
Intervention groups
Intervention group: For patients in the first group, aspirin (Jalinous, Iran) is discontinued 7 days before surgery. Control group: 80 mg Aspirin, single dose is prescribed before surgery and will continue.
Main outcome variables
Postoperative pain; Postoperative complications (hematoma, infection, Bleeding)

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20171213037857N2**
Registration date: **2018-11-30, 1397/09/09**
Registration timing: **registered_while_recruiting**
Last update: **2018-11-30, 1397/09/09**
Update count: **0**
Registration date
2018-11-30, 1397/09/09

Registrant information
Name
Ali Zahedian Tijeneki
Name of organization / entity
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-06-22, 1397/04/01
Expected recruitment end date
2019-02-20, 1397/12/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of discontinuation of aspirin on complications of inguinal hernia surgery in patients receiving aspirin

Public title
The effect of discontinuation of aspirin on complication of inguinal hernia surgery
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:

Inguinal hernia Age over 18 years old Daily aspirin therapy

Exclusion criteria:

Patients with unstable angina Congestive Heart Failure Shock Aspirin sensitivity History of gastrointestinal and cerebral hemorrhage Patients treated with warfarin, plavix and methotrexate

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Samples will be divided into two groups by a simple random method. In this research, the coin toss will be used to create a random sequence in a two-group trial. So that one of the study groups is tail and the other group is considered as a head, and according to the sample size, the same amount of coin is tossed and the subjects are divided into two groups of random allocation.

Blinding (investigator's opinion)

Not 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 Babol University of Medical Sciences

Street address

Babol University of Medical Sciences, Ganjafrooz Street, Babol, Mazandaran, Iran

City

Babol

Province

Mazandaran

Postal code

4716681451

Approval date

2018-05-27, 1397/03/06

Ethics committee reference number

IR.MUBABOL.HRI.REC.1397.051

Health conditions studied

1

Description of health condition studied

Inguinal hernia

ICD-10 code

K40

ICD-10 code description

Inguinal hernia

Primary outcomes

1

Description

Bleeding

Timepoint

During the operation, Immediately after surgery

Method of measurement

Number of consumed gases

2

Description

Postoperative hematoma

Timepoint

12 and 24 hours after surgery

Method of measurement

Clinical examination

3

Description

Postoperative complications

Timepoint

7 days after surgery

Method of measurement

Clinical examination

4

Description

Postoperative pain

Timepoint

4, 8, 12 hours after surgery

Method of measurement

Visual Analog Scale questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Aspirin 80 mg will be discontinued (Jalinous, Iran) 7 days before surgery.

Category

Prevention

2

Description
Control group: 80 mg Aspirin (Jalinous, Iran) single dose is prescribed before surgery and will continue.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshti Hospital in Babol
Full name of responsible person
Dr. Ali Zahedian
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Shahid Beheshti Hospital in Babol; Shahid Sargord Ghasemi Street; Babol; Iran
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2

Recruitment center
Name of recruitment center
Ayatollah Rouhani educaional medical center- Babol
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Dr. Reza Ghadimi
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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
Babol University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
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
Babol University of Medical Sciences
Full name of responsible person
Dr. Shokoufeh Hassannia
Position
General Surgery Resident
Latest degree
Medical doctor
Other areas of specialty/work
General Surgery
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Person responsible for scientific inquiries

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Assistant Professor

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Person responsible for updating data

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Latest degree

Medical doctor

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Web page address

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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

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable