

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

Country

Iran (Islamic Republic of)

Phone

+98 11 3225 6285

Email address

a.zahedian@mubabol.ac.ir

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

Street address

Shahid Beheshti Hospital in Babol; Shahid Sargord Ghasemi Street; Babol; Iran

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Recruitment center

Name of recruitment center

Ayatollah Rouhani educaional medical center- Babol

Full name of responsible person

Dr. Ali Zahedian

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Ayatollah Rouhani educaional medical center in Babol; Ganjafrooz Street; Babol; Iran

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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

Street address

Babol University of Medical Sciences; Ganjafrooz Street; Babol; Iran

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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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Surgery Department, Shahid Beheshti Hospital, Shahid Sargord Ghaemi St. Babol

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Assistant Professor

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Person responsible for updating data

Contact

Name of organization / entity

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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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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