Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jul 2026

Evaluation of aspirin resistance in different doses of ASA by bleeding time

Protocol summary

Summary

This is a double blind, placebo controlled, parallel designed randomized clinical trial on 370 subjects referred to clinical offices in Broujerd city.The volunteer subjects are divided into five groups based on consumption of different doses of aspirin. Written informed consent will be obtained from the patients and their medical history is recorded according to a designed questionnaire. Inclusion criteria: All subjects age 35 and older Exclusion criteria comprise of past medical history of congenital or acquired coagulation disorders , renal failure,blood cell dyscrasia, use of medications affecting blood cells, platelets less than 150000, simultaneous use of other anti platelets and anticoagulants like warfarin and previous history of hypersensitivity to aspirin. Patients are divided into four testing groups :testing group 1 (ASA 80 mg per day) ,testing group 2 (ASA 81 mg per day), testing group 3 (ASA100 mg per day),testing group 4 (ASA 325 mg per day) and one control group of placebo.Thereafter the participants Bleeding time will be tested using Ivy method and urinary Thromboxane B2.since the technique is painful this test will be performed just once for each participant after using aspirin . In case of different interpretation of the results of one participant, the mean of the results will be considered. Participants will be tested for other tests which affect bleeding time and blood group will also be tested. Aspirin resistance is defined as no increment of bleeding time more than normal upper limit of bleeding time.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201202026958N3**
Registration date: **2012-06-07, 1391/03/18**
Registration timing: **prospective**
Last update:
Update count: **0**

Registration date

2012-06-07, 1391/03/18

Registrant information

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Recruitment status

Recruitment complete

Funding source

Lorestan University of Medical Sciences

Expected recruitment start date

2012-07-01, 1391/04/11

Expected recruitment end date

2013-01-30, 1391/11/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of aspirin resistance in different doses of ASA by bleeding time

Public title

Evaluation of aspirin resistance in different doses of aspirin

Purpose

Diagnostic

Inclusion/Exclusion criteria
Inclusion criteria: All participants 35 years old and older , who are living in Borujerd city.Participants should have used ASA at least for 5 days. Exclusion criteria: History of acquired or congenital coagulation disorders ,chronic kidney diseases and blood discrasia were excluded from the study. Consumption of some medications such as other platelet inhibitors and anticoagulants such as warfarin ; and volunteers with platelet count less than 150000.

Age
From **35 years** old to **149 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **370**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Lorestan University of Medical Sienceses

Street address
Kamalvand Research Center

City
Khoramabad

Postal code

Approval date
2012-01-31, 1390/11/11

Ethics committee reference number
200/61140

Health conditions studied

1

Description of health condition studied
Aspirin resistance

ICD-10 code
Y45.1

ICD-10 code description
Salicylates

Primary outcomes

1

Description
Bleeding time and urinary thromboxane B2

Timepoint
Once , after intervention

Method of measurement
IVY method

2

Description
Thromboxane B2

Timepoint
Once after intervention

Method of measurement
Urinary sample

Secondary outcomes

empty

Intervention groups

1

Description
Testing group1: aspirin (80 mg) , 1 pill per day

Category
Diagnosis

2

Description
Testing group 2: aspirin (81mg), 1 pill per day

Category
Diagnosis

3

Description
Testing group3: aspirin (100 mg), 1 pill per day

Category
Diagnosis

4

Description
Testing group4: aspirin (325 mg), 1 pill per day

Category
Diagnosis

5

Description
Control group : placebo, 1 pill per day

Category
Diagnosis

Recruitment centers

1

Recruitment center
Name of recruitment center
Dr Maleki Office
Full name of responsible person
Dr Ali Maleki
Street address
N.11, Mehr Medical center
City
Broujerd

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Lorestan University of Medical Sciences
Full name of responsible person
Dr Mohammadhassan Kaedi
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Kamalvand, Research center
City
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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
Lorestan 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

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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