Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

Name
Ali Maleki
Name of organization / entity
Lorestan university of medical siences
Country
Iran (Islamic Republic of)
Phone
+98 66 2353 8057
Email address
maleki.a@lums.ac.ir

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
Street address
Kamalvand, Research center
City
Khoramabad
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

Contact
Name of organization / entity
Lorestan University of Medical Sciences
Full name of responsible person
Dr Ali Maleki
Position
Assistant Professor
Other areas of specialty/work
Street address
N15, Ostad Davami 4 , Shahid Beheshti Street
City
Broujerd
Postal code
6916726611
Phone
+98 66 2353 8057
Fax
+98 66 2353 8057
Email
maleki.a@lums.ac.ir dralimaleki@yahoo.com
Web page address
dralimaleki.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Lorestan University of Medical Sciences
Full name of responsible person
Dr Ali Maleki
Position
Cardiologist
Other areas of specialty/work
Street address
N15, Ostad Davami4 , Shahid Beheshti Street
City
Broujerd
Postal code
6916716611
Phone
+98 66 2353 8057
Fax
+98 66 2353 8057
Email
dralimaleki@yahoo.com maleki.a@lums.ac.ir
Web page address
dralimaleki.com

Person responsible for updating data

Contact
Name of organization / entity
Lorestan University of Medical Sciiences
Full name of responsible person
Dr Negin Rashidii
Position
Internist
Other areas of specialty/work
Street address
N 8, Roohbakhshan street ,Takhti Street
City
Broujerd
Postal code
6916716611
Phone
+98 66 2530 3363
Fax
+98 66 2353 8057
Email
rashidin@razi.tums.ac.ir negin_rashidi@hotmail.com
Web page address

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