

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The investigation of the effectiveness of ASA usage on the incidence of cardiovascular events in patients with corona virus (COVID-19) A clinical trial study

Protocol summary

Study aim

Determining of the effectiveness of ASA usage on the incidence of cardiovascular events in patients with corona virus (COVID-19) in Rasht in 2020.

Design

Clinical trial with control group, with parallel groups, single blind, randomized, phase 2 on 36 patients. Random permutation block method will be used to assign treatment to the subjects. Therefore, considering that group A is patients who are taking aspirin 80 mg and group B is the group who are not taking aspirin 80 mg. The complete randomization file is available as an Excel file (randomization is done with SAS software version 9

Settings and conduct

Patients diagnosed with Covid 19 are randomly divided into two groups receiving aspirin 80 mg for three months and the group not receiving aspirin. Demographic and clinical information is then obtained from the patient by the physician. Patients in the intervention group will be followed up for six months (during these three months as well as three months later). This research will be single blind. Patients and data analysts and researchers evaluate blind outcome.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All patients admitted to Razi Hospital over 18 years of age based on CT scan or PCR diagnosis of COVID 19 Exclusion criteria: patients admitted to the ICU, Patients with a history of ulcers and gastrointestinal problems, patients receiving aspirin, patients with a history of thrombotic events such as heart attack or stroke or a history of atrial fibrillation, congestive heart failure, active bleeding or coagulation disorders such as thrombocytopenia.

Intervention groups

Patients are randomly divided into two intervention groups receiving aspirin and the control group not receiving aspirin.

Main outcome variables

Incidence of cardiovascular events

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180205038626N7**

Registration date: **2020-12-27, 1399/10/07**

Registration timing: **registered_while_recruiting**

Last update: **2020-12-27, 1399/10/07**

Update count: **0**

Registration date

2020-12-27, 1399/10/07

Registrant information

Name

Zahra Ahmadnia

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 3361 8177

Email address

zahmadnia@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-05, 1399/09/15

Expected recruitment end date

2021-04-04, 1400/01/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The investigation of the effectiveness of ASA usage on the incidence of cardiovascular events in patients with corona virus (COVID-19) A clinical trial study

Public title
The investigation of the effectiveness of ASA usage on corona virus

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
All patients admitted with a diagnosis of Covid 19 based on CT scan or PCR Over 18 years
Exclusion criteria:
patients admitted to the ICU. Patients with a history of ulcers and gastrointestinal problems. Patients receiving aspirin. patients with a history of thrombotic events such as heart attack or stroke or a history of atrial fibrillation, congestive heart failure, active bleeding or coagulation disorders such as thrombocytopenia.

Age
From **18 years** old

Gender
Both

Phase
2

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **36**

Randomization (investigator's opinion)
Randomized

Randomization description
In order to allocate treatment to the subjects, randomized permutation block method and considering six hex blocks, 6 blocks will be produced for 36 patients. Therefore, considering that group A is patients who are taking aspirin 80 mg and group B is the group who are not taking aspirin 80 mg. The complete randomization file is available as an Excel file (randomization is done with SAS software version 9).

Blinding (investigator's opinion)
Single blinded

Blinding description
The two groups studied can be divided into two letters (A group receiving aspirin) and B (group not receiving drugs) in the form of a sealed envelope to the evaluating researcher, and at the end the envelope will be opened and it will be determined that What are the treatments A and B.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Guilan University of Medical Sciences

Street address

Rasht, Namjoo Ave., Shahid Siadati St., Faced to the 17th Shahrivar Hospital, Old Building, School of Health, University of Technology Research and Technology

City

Rasht

Province

Guilan

Postal code

41446-66949

Approval date

2020-11-09, 1399/08/19

Ethics committee reference number

IR.GUMS.REC.1399.372

Health conditions studied

1

Description of health condition studied

COVID-19 disease

ICD-10 code

U07. 1

ICD-10 code description

COVID-19

Primary outcomes

1

Description

Thromboembolic events

Timepoint

Thromboembolic events at the beginning of the study and 3 and 6 months later

Method of measurement

Clinical signs and laboratory tests

2

Description

Cardiovascular accidents

Timepoint

Cardiovascular accidents at the beginning of the study and 3 and 6 months later

Method of measurement

Electrocardiography, Echocardiography

3

Description

Brain accidents

Timepoint

Brain accidents at the beginning of the study and 3 and 6 months later

Method of measurement

CT scan

Secondary outcomes

1

Description

Death

Timepoint

6 months later

Method of measurement

Phone call with the patient

Intervention groups

1

Description

Intervention group: Patients with covid 19 were treated daily with aspirin 80 mg for three months.

Category

Treatment - Drugs

2

Description

Control group: Patients with covid19 received standard treatment for three months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi Hospital, Rasht

Full name of responsible person

Zahra ahmadnia

Street address

Razi Educational and Medical Center, Sardar Jangal St

City

Rasht

Province

Guilan

Postal code

41448

Phone

+98 13 3354 1001

Email

razi.hospital@yahoo.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Mohammadreza Naghipour

Street address

Namjoo Ave., Shahid Siadati St., Rasht., Technology & Research Vice-chancellor of University

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41446-66949

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+98 13 3333 5821

Email

naghi@gums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Rasht 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

Rasht University of Medical Sciences

Full name of responsible person

Zahra ahmadnia

Position

Nursery

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Dr. Heshmat Rasht Hospital -Masala Square, Baniyan St

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4193955588

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

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Position

Nursery

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Master

Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Title and more details about the data/document

Information on the main outcome

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

Request to receive unidentifiable personal data or other documents

From where data/document is obtainable

Dr, Elham Ramezanzadeh

What processes are involved for a request to access data/document

By email to Dr. Elham Ramezanzadeh

Comments