

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Study of the safety and clinical outcomes of fasting comparing to non-fasting before elective coronary angiography: A randomized clinical trial

Protocol summary

Study aim

Reducing the complications caused by fasting and presenting the non-fasting protocol to doctors in order to perform the angiography procedure as best as possible.

Design

Clinical trial with a control group, randomized, on 292 patients. The stratified block randomization method will be used for randomization.

Settings and conduct

This randomized clinical trial will be performed in Dr. Heshmat Heart Hospital in Rasht during 2023-2024. Participants will be randomly divided into fasting and non-fasting groups. Demographic information of the patients including age, sex, body mass index, condition of underlying diseases, the use of oral hypoglycemic drugs or injectable insulin, the history of hypoglycemia, the rate of pulmonary aspiration during the procedure, the rate of hypoglycemia in the duration of fasting, gastrointestinal symptoms, vasovagal occurrence during the procedure and when the sheet is removed, the prevalence of hypotension, as well as the patient's satisfaction with the entire procedure will be collected and recorded. All these outcomes will be evaluated during and immediately after the completion of coronary angiography.

Participants/Inclusion and exclusion criteria

All patients who are candidates for elective angiography will be entered to the study. If the patient undergoes emergency, complicated, incomplete or unsuccessful angiography, has recently experienced symptoms of dizziness and convulsions, or is pregnant, or has swallowing disorders, feeding with digestive tubes, will be excluded.

Intervention groups

In the intervention group 146 candidates for elective coronary angiography will not fast before it and are allowed to consume food and liquids in any amount.

Main outcome variables

Occurrence of pulmonary aspiration during the

procedure, occurrence of hypoglycemia during fasting and blood pressure reduction, occurrence of vasovagal during sheet removal.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220809055645N3**

Registration date: **2023-05-20, 1402/02/30**

Registration timing: **prospective**

Last update: **2023-05-20, 1402/02/30**

Update count: **0**

Registration date

2023-05-20, 1402/02/30

Registrant information

Name

Fatemeh Baharvand

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 3361 8177

Email address

dr.baharcadio@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-22, 1402/03/01

Expected recruitment end date

2024-05-21, 1403/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Study of the safety and clinical outcomes of fasting comparing to non-fasting before elective coronary angiography: A randomized clinical trial

Public title
Study of the safety and clinical outcomes of fasting comparing to non-fasting before elective coronary angiography

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
All patients over 18 years of age who are candidates for elective angiography at Dr. Heshmat Hospital in Rasht during the period of 2022-2023
Exclusion criteria:
Emergency, complicated, incomplete or unsuccessful angiography Patients with swallowing disorders, feeding with digestive tubes Patients with symptoms of dizziness and seizures Pregnant

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **292**

Randomization (investigator's opinion)
Randomized

Randomization description
The method of sampling and randomization of this clinical trial study will be stratified blocked randomization method. In this way, each person was randomly assigned to the intervention or control group using 4 random blocks in a ratio of 1:1. In this method, one of the letters A or B will be assigned to each group.

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 Guilan University of Medical Sciences

Street address

Cardiovascular Disease Research Center, Dr Heshmat Heart Hospital, 15th of Khordad Street, Mosalla Square, Guilan, Rasht, Iran

City

rasht

Province

Guilan

Postal code

4193955588

Approval date

2023-04-19, 1402/01/30

Ethics committee reference number

IR.GUMS.REC.1402.032

Health conditions studied

1

Description of health condition studied

Ischemic heart disease

ICD-10 code

ICD-10 code description

coronar

Primary outcomes

1

Description

Occurrence of pulmonary aspiration during the procedure, occurrence of hypoglycemia during fasting and blood pressure drop, occurrence of vasovagal during sheet removal.

Timepoint

The time period for measuring these results is until the sheet is removed, which will be 3 hours after the procedure for angiography and 4 hours after the procedure for angioplasty.

Method of measurement

The method of measurement for the studied samples will be the researcher-made checklist .

Secondary outcomes

1

Description

Gastrointestinal symptoms and patient satisfaction with the procedure

Timepoint

The time period for measuring these results is until the sheet is removed, which will be 3 hours after the procedure for angiography and 4 hours after the procedure for angioplasty.

Method of measurement

The method of measurement for the studied samples will be the researcher-made checklist.

Intervention groups

1

Description

Intervention group: The intervention group will include 146 candidates for elective coronary angiography, who will enter the study with personal consent and after completing the informed consent form. The participants in this group will not fast before the angiography and are allowed to consume food and liquids in any amount. All patients over 18 years of age who are candidates for elective angiography in Dr. Heshmat Rasht Hospital during the period of 2014-2014 will be included in the study. If the patient undergoes emergency, complicated, incomplete or unsuccessful angiography, or if they have swallowing disorders, feeding with digestive tubes, they will be excluded from the study. In addition, if the patient has symptoms of dizziness and convulsions recently or is pregnant, she will be excluded from the study.

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Heshmat Heart Hospital

Full name of responsible person

Fatemeh Baharvand

Street address

Cardiovascular Disease Research Center, Dr Heshmat Heart Hospital, 15th of Khordad Street, Mosalla Square,, Guilan, Rasht, Iran

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dr.baharcadio@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Mohammadreza Naghipour

Street address

Cardiovascular Diseases Research Center, Dr. Heshmat Rasht Hospital, 5th of Khordad Street, Mosalla Square, Guilan, Rasht, 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

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

Fatemeh Baharvand

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Cardiology

Street address

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Person responsible for scientific inquiries

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Patients' information will be kept confidential and it will be only available to this project's researchers.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

Yes - There is 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

No - There is not a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Parts of the data, such as information related to the main outcomes can be shared

When the data will become available and for how long

"Starting the access period 2 years after the results are published"

To whom data/document is available

Researchers of the study

Under which criteria data/document could be used

Journal if needed

From where data/document is obtainable

Fatemeh Baharvand

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

Request for data should be sent via email to Dr. Fatemeh Baharvand. dr.baharcadio@gmail.com

Comments

Person responsible for updating data

Contact

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Fatemeh Baharvand

Position

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Latest degree

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Other areas of specialty/work

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