

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

Evaluation of oral Glutamine administration on myocardial damage following non-ST elevation myocardial infarction, Double blind randomized clinical trial study

Protocol summary

Study aim

Evaluation of glutamine administration on myocardial damage following non-ST elevation myocardial infarction

Design

The randomized clinical trial with the intervention and control group, parallel groups, double blinded

Settings and conduct

A randomized clinical trial that is performed on patients undergoing non-emergency myocardial infarction who are referred to Fatemeh Zahra Hospital in Sari. The population studied in this study includes all adult patients (aged 18-80) including men and women who have inclusion criteria for research. Patients and therapists are not aware of the type of drug contained in powders (glutamine, Avicel and starch), and only the researcher knows the code based on the code (code A or code B)

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age over 18 years NSTEMI patients Normal function of liver, renal system, pulmonary system and thyroid Exclusion criteria: Emergency patients Serious water and electrolyte disorders Unwillingness to co-operate with the patient History of chronic lung, liver, kidney and thyroid diseases and heart failure Age over 80 years Pregnant and lactating women Patients who are hypersensitive to glutamine or who are banned in any way by their administration of glutamine Total Bilirubin more than 10 mg / dL Creatinine clearance less than 30 ml / min Absolute Absence of Intestinal Feeding

Intervention groups

A total of 106 patients with open heart surgery candidates were randomly divided into two groups of 53. For the first group, 0.5 g / kg of glutamine is taken orally once a day, and for the control group, placebo (Avicel and starch powder) is added. The drug forms of placebo are prepared in terms of the appearance of glutamine.

Main outcome variables

Duration of admission to CCU, Duration of hospitalization, Mortality after MI

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151109024975N12**

Registration date: **2019-06-30, 1398/04/09**

Registration timing: **retrospective**

Last update: **2019-06-30, 1398/04/09**

Update count: **0**

Registration date

2019-06-30, 1398/04/09

Registrant information

Name

Gohar Eslami

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 11 3354 3695

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-22, 1397/09/01

Expected recruitment end date

2019-05-20, 1398/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of oral Glutamine administration on myocardial damage following non-ST elevation myocardial infarction, Double blind randomized clinical trial study

Public title

Effect of Glutamine on Reducing Myocardial Damage

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age over 18 years NSTEMI patients Normal function of liver, renal system, pulmonary system and thyroid

Exclusion criteria:

Emergency patients Serious water and electrolyte disorders Unwillingness to co-operate with the patient History of chronic lung, liver, kidney and thyroid diseases and heart failure Age over 80 years Pregnant and lactating women Patients who are hypersensitive to glutamine or who are banned in any way by their administration of glutamine Total Bilirubin more than 10 mg / dL Creatinine clearance less than 30 ml / min Absolute Absence of Intestinal Feeding

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **106**

Randomization (investigator's opinion)

Randomized

Randomization description

Random method and description of each method: simple randomization After determining the size of the sample, 106 people, 53 in the control group and 53 in the intervention group were considered. By co-ordinating medical records, this number was considered average for the duration of the appointment, and then the list of individuals was determined. The list was prepared based on the patients' turn-by-turn and then, using the random numbers table, the numbers of the control and intervention group were determined and compared to the coordination for the next steps

Blinding (investigator's opinion)

Double blinded

Blinding description

In the informed consent form, patients are told that they may receive glutamine or placebo (Avicel powder and starch). Therefore, patients are not aware of their

treatment group. Since patients and therapists are not aware of the type of drug contained in powders (glutamine, Avicel and starch), only the researcher is aware of the powder on the package code (code A or code B).

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

- Ethics committee of Mazandaran University of Medical Sciences

Street address

Artesh Blvd., Fatemeh-zahra hospital Mazandaran University of Medical Sciences

City

sari

Province

Mazandaran

Postal code

48157-33971

Approval date

2018-11-19, 1397/08/28

Ethics committee reference number

IR.MAZUMS.REC.1397.324

Health conditions studied**1****Description of health condition studied**

Non ST elevation myocardial infarction

ICD-10 code

I24.0

ICD-10 code description

Acute coronary thrombosis not resulting in myocardial infarction

Primary outcomes**1****Description**

NonST elevation myocardial infarction

Timepoint

After diagnosis of myocardial infarction without ST elevation, an increase in Troponin and CK-MB in the first three days of hospitalization

Method of measurement

TIMI score

Secondary outcomes

1

Description

Duration of admission to CCU

Timepoint

Duration of admission

Method of measurement

Patients follow up

2

Description

Mortality

Timepoint

Duration of admission

Method of measurement

Patients follow up

Intervention groups

1

Description

Intervention group: A dose of 0.5 g / kg of glutamine powder is administered orally once a day for 3 days of hospitalization

Category

Treatment - Drugs

2

Description

Control group: Patients in the control group received placebo (Avicel powder and starch). The frequency and duration of use of placebo in the control group were similar to oral administration of glutamine powder in the intervention group (once a day for 3 days of hospitalization)The placebo is structurally similar to glutamate powder.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemeh-zahra hospital Mazandaran University of Medical Sciences

Full name of responsible person

Gohar Eslami

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Artesh Blvd., Center of the heart of Mazandaran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Majid Saeedi

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Vice Chancellor for Research of Mazandaran University of Medical Sciences, Moalem Square

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Grant name

Grant code / Reference number

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

No

Title of funding source

Sari 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

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Gohar Eslami

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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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

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