Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 infraction

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 infraction 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 Scienses

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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 Scienses
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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 Scienses
Full name of responsible person
Gohar Eslami
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Sponsors / Funding sources

1

Sponsor
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Full name of responsible person
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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
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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