

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

Assessment of lactic acidosis associated with Metformin useage in Diabetic patients undergoing coronary angiography

Protocol summary

Study aim

Determination of lactic acidosis associated with Metformin usage in patients with type 2 diabetes undergone coronary angiography

Design

Clinical trial has a control group, with parallel and randomized groups

Settings and conduct

In this study, which is performed at Rajaei Hospital in Karaj, we continue to prescribe metformin in the intervention group before coronary angiography and up to 48 hours after that, and their lactic acid and pH levels are monitored within 48 hours. In the control group, we discontinue metformin 48 hours after angiography and control their lactic acid and blood pH

Participants/Inclusion and exclusion criteria

Inclusion: 1) Patient with type 2 diabetes with a history of metformin usage who has undergone coronary angiography 2) The GFR before angiography is equal to or greater than 60 ml per minute 3) Patient's systolic blood pressure is equal to or greater than 90 mm Hg 4) Serum creatinine levels before angiography are less than 1.49 mg in males and less than 1.40 mg / dL in females 5) The patient's plasma pH should be 7.45-7.35 before angiography Exclusion: 1) Critical physical condition requires immediate intervention 2) Failure to perform PH or creatinine sampling and lactate levels after angiography 3) Sepsis and other conditions that cause lactic acidosis 4) Discontinuation of metformin by the patient 5) Diarrhea, vomiting, and other conditions that predispose the patient to dehydration 6) Increase serum creatinine by more than 1.5 mg / dL

Intervention groups

Intervention group: We continue the metformin usage before the angiography till 48 hours after the angiography. During these 48 hours, we follow up the patients and measure their plasma lactic acid levels and blood pH Control group: In these patients, we discontinue metformin usage up to 48 hours after angiography and

control their lactic acid and blood pH

Main outcome variables

Lactic acidosis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200201046329N1**

Registration date: **2020-05-02, 1399/02/13**

Registration timing: **retrospective**

Last update: **2020-05-02, 1399/02/13**

Update count: **0**

Registration date

2020-05-02, 1399/02/13

Registrant information

Name

Mohamad Jalali

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 26 3452 4882

Email address

mdrjalali@abzums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-22, 1397/09/01

Expected recruitment end date

2019-11-22, 1398/09/01

Actual recruitment start date

2018-12-22, 1397/10/01

Actual recruitment end date

2019-09-23, 1398/07/01
Trial completion date
2019-09-23, 1398/07/01

Scientific title
Assessment of lactic acidosis associated with Metformin useage in Diabetic patients undergoing coronary angiography

Public title
Assessment of lactic acidosis associated with Metformin usage

Purpose
Basic scienece

Inclusion/Exclusion criteria
Inclusion criteria:
Patient with type 2 diabetes who has undergone coronary angiography The GFR before angiography is equal to or greater than 60 ml per minute Patient with diabetes with a history of metformin usage Patient's Ejection Fraction is equal to or greater than 45% Patient's systolic blood pressure is equal to or greater than 90 mm Hg Serum creatinine levels before angiography are less than 1.49 mg in males and less than 1.40 mg / ml in females The patient's plasma pH should be 7.45-7.35 before angiography
Exclusion criteria:
Critical physical condition requires immediate intervention Failure to perform PH or creatinine sampling and lactate levels after angiography Sepsis and other conditions that cause lactic acidosis Discontinuation of metformin usage by the patient Diarrhea, vomiting, and other conditions that predispose the patient to dehydration Increase serum creatinine by more than 1.5 mg / dL

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **200**
Actual sample size reached: **200**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization:The card shuffling method will be used.in this method, we prepare an equal number of interventions and controls cards for both groups and after merging the cards, by assigning the number to the samples, for each sample, we remove the card at the same time. If the card is out of the control group, that person is in the control group, and if the intervention card is out, the person is in the group. It will be an intervention

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 AlborzUniversity of Medical Sciences

Street address

Safarian Alley ,Golshahr,Deputy of Research and Technology

City

Karaj

Province

Alborz

Postal code

3198537646

Approval date

2018-10-13, 1397/07/21

Ethics committee reference number

IR.ABZUMS.REC.1397.180

Health conditions studied

1

Description of health condition studied

Lactic acidosis

ICD-10 code

I25.1

ICD-10 code description

Atherosclerotic heart disease

Primary outcomes

1

Description

Lactic acidosis

Timepoint

Before the intervention and after coronary angiography up to 48 hours

Method of measurement

blood sampling

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: We continue to prescribe metformin before the angiography and up to 48 hours after the angiography. During these 48 hours, we follow up the patients and measure their plasma lactic acid levels and blood pH. In case of dehydration, we hydrate patients with normal saline serum to prevent lactic acidosis due to dehydration

Category

Other

2

Description

Control group: Up to 48 hours after angiography, we discontinue prescription of metformin and control their lactic acid and blood pH.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Rajaei Hospital

Full name of responsible person

Mohammad Jalali

Street address

Rajaei Ave ,Hesarak,Shahid Beheshti Blvd,Rajaei Hospital

City

Karaj

Province

Alborz

Postal code

3197635141

Phone

+98 26 3457 0030

Email

rajaei@abzums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Alborz University of Medical Sciences

Full name of responsible person

Mohammad Nourisepehr

Street address

Safarian Alley ,Golshahr,Deputy of Research and Technology

City

Karaj

Province

Alborz

Postal code

3198537646

Phone

+98 26 3463 3705

Email

Research@abzums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Alborz 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

Alborz University of Medical Sciences

Full name of responsible person

Mohammad Jalali

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Cardiology

Street address

Rajaei Ave ,Hesarak,Shahid Beheshti Blvd,Rajaei Hospital

City

Karaj

Province

Alborz

Postal code

3197635141

Phone

+98 26 3457 0030

Email

mdrjalali@abzums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Alborz University of Medical Sciences

Full name of responsible person

Mohammad Jalali

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Cardiology

Street address

Rajaei Ave ,Hesarak,Shahid Beheshti Blvd,Rajaei Hospital

City

Karaj

Province

Alborz

Postal code

3197635141

Phone

+98 26 3457 0030

Email

mdrjalali@abzums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Alborz University of Medical Sciences

Full name of responsible person

Mohammad Jalali

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Cardiology

Street address

Rajaei Ave ,Hesarak,Shahid Beheshti Blvd,Rajaei

Hospital

City

Karaj

Province

Alborz

Postal code

3197635141

Phone

+98 26 3457 0030

Email

mdrjalali@abzums.ac.ir

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

Not applicable

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

Not applicable

Data Dictionary

Not applicable