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

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Alborz

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3197635141

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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

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Safarian Alley ,Golshahr,Deputy of Research and Technology

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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

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Person responsible for updating data

Contact

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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

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