Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of carbon dioxide gas and contrast agent on kidney function in patients peripheral vascular disease

Protocol summary

Study aim
The purpose of this study was to compare the effect of CO2 and contrast media on the occurrence of nephropathy in patients undergoing angiography or angioplasty of the lower extremity.

Design
A single-blind, parallel controlled, randomized clinical trial is performed on 166 eligible patients.

Settings and conduct
This study is single blind and patients are not aware of the type of intervention.Both groups receive Ejection Fraction (EF) -based hydration 12 hours before the procedure and 6 hours after the procedure. Patients in the co2 group receive a maximum of 60 cc of CO2 gas with a maximum of 20 cc of contrast agents (if needed) during diagnostic or therapeutic action. The contrast-receiving group will be diagnosed or treated with a maximum of 500 cc through the artery sheath.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age over 18 years Estimated Glomerular filtration rate (GFR) greater than 30 ml / min /1.73 m2 based on Modification of Diet in Renal Disease (MDRD) equation. Exclusion criteria: Contact contrast over the past month Patients with intracardiac shunt, History of kidney or heart transplantation, More than 15% change in serum creatinine level over the past two days, Patients undergo regular hemodialysis, Patients with a history of proteinuria and Cirrhotic patients.

Intervention groups
Patients groups: 1.angiography or angioplasty of the lower extremities with CO2 gas 2.angiography or angioplasty of the lower extremities with contrast media.

Main outcome variables
Contrast induce acute kidney injury

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20191107045359N1**
Registration date: **2019-12-18, 1398/09/27**
Registration timing: **registered_while_recruiting**

Last update: **2019-12-18, 1398/09/27**
Update count: **0**

Registration date
2019-12-18, 1398/09/27

Registrant information

Name
Batoul Naghavi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 2266 3246

Email address
naghavirhc@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-11-22, 1398/09/01

Expected recruitment end date
2020-11-21, 1399/09/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of carbon dioxide gas and contrast agent on kidney function in patients peripheral vascular disease

Public title

The effect of carbon dioxide gas on the occurrence of nephropathy

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria:

Age over 18 years Estimated GFR greater than 30 ml / min /1.73 m2 based on MDRD equation

Exclusion criteria:

Contact contrast over the past month Patients with intracardiac shunt History of kidney or heart transplantation More than 15% change in serum creatinine level over the past two days Patients undergo regular hemodialysis Patients with a history of proteinuria Cirrhotic patients

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **166**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization The computer generates random numbers between 0 and 1. If the random number is less than 0.500, the person enters group T. If the random number is greater than 0.500, the person enters group C.

Blinding (investigator's opinion)

Single blinded

Blinding description

After obtaining informed consent, patients are divided into two groups based on random numbers, but the patients do not know which groups they belong to.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Rajaie Cardiovascular, Medical and Research Center

Street address

Vali Asr Ave, Next to Mellat Park, Rajaie Cardiovascular, Medical and Research Center

City

Tehran

Province

Tehran

Postal code

1995614331

Approval date

2019-10-26, 1398/08/04

Ethics committee reference number

IR.RHC.REC.1398.055

Health conditions studied

1

Description of health condition studied

Peripheral vascular diseases

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Contrast induce acute kidney injury.Nephropathy will be defined based on a 25% or 0.5 mg / dl increase in serum creatinine.

Timepoint

Before intervention and 48 hours after intervention.

Method of measurement

laboratory kit

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Angiography or angioplasty with CO2 gas

Category

Diagnosis

2

Description

Control group: Angiography or angioplasty with contrast media

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Rajaie Cardiovascular, Medical and Research Center

Full name of responsible person

Batool Naghavi

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Vali Asr Ave, Next to Mellat Park, Rajaie Cardiovascular, Medical and Research Center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Rajaie Cardiovascular, Medical and Research Center

Full name of responsible person
Dr.Fereidoun Nouhi

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Web page address
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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
Rajaie Cardiovascular, Medical and Research Center

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
Iran University of Medical Sciences

Full name of responsible person
Batoul Naghavi

Position
Cardiologist

Latest degree
Specialist

Other areas of specialty/work
Cardiology

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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
No more information

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
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available