

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 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

Street address

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

City

Tehran

Province

Tehran

Postal code

1995614331

Phone

+98 21 23921

Fax

+98 21 2204 2026

Email

naghavirhc@gmail.com

Web page address

<http://rhc.ac.ir/fa>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rajaie Cardiovascular, Medical and Research Center

Full name of responsible person

Dr.Fereidoun Nouhi

Street address

Valiasr Ave, Rajaie Cardiovascular, Medical and
Research Center

City

Tehran

Province

Tehran

Postal code

1995614331

Phone

+98 21 23921

Fax

+98 21 2204 2026

Email

Naghavirhc@gmail.com

Web page address

<http://rhc.ac.ir/fa>

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

Street address

Hashemi rafsanjani highway,Rajaie Cardiovascular,
Medical and Research Center.postal code
:1995614331

City

Tehran

Province

Tehran

Postal code

1995614331

Phone

+98 21 2266 3246

Fax

Email

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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