Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparative study of the effect of oral liquid therapy with intravenous fluid therapy on the adequacy of renal function after angiography and angioplasty

Protocol summary

Study aim

Comparative study of the type of fluid therapy on the adequacy of kidney function in patients undergoing angiography and angioplasty

Design

A clinical trial with a community-based, pragmatic, venous and oral group, with parallel,Without blinding, non-randomized groups

Settings and conduct

The patients are candidates for angiography and angioplasty in Heshmatieyeh Hospital in Sabzevar who are elective and have entry criteria are takes Conscious informed consent and age, weight, creatinine and EF calculates And creatinine below 1.5 is consider normal and the patient's GFR is calculated. The first patient that is candidate for angioplasty and angiography who has been selected to disposal, will be drafted in one of the two groups of venous or oral fluid therapy.We will assign the next patients in each of these two groups, respectively. In all groups, 500 ml of normal saline serum is infusion intravenously 6 hours before the procedure as basal hydration.then, for the oral group 300 cc of mineral water was gived 2 hours before the procedure and 700 cc of mineral water within 6 hours after the procedure, and for the intravenous group 300 cc normal saline was administered 2 hours before the procedure and 700 cc normal saline get infusion within 6 hours after the procedure. the creatinine patient's blood is checked 48 hours after the procedure and Creatinine levels are compared with before intervention

Participants/Inclusion and exclusion criteria

Patients with an EF of more than 35% have creatinine less than 1.5, patients with no ESRD [1]

Intervention groups

Oral and venous fluid therapy in patients undergoing angiography and in patients undergoing angioplasty

Main outcome variables

Creatinine changes before angiography and angioplasty; Creatinine levels after angiography and angioplasty

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181122041722N1**
Registration date: **2018-12-15, 1397/09/24**
Registration timing: **registered_while_recruiting**

Last update: **2018-12-15, 1397/09/24**
Update count: **0**

Registration date

2018-12-15, 1397/09/24

Registrant information

Name

Khadijeh Karraby

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 51 4464 7891

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-03, 1397/09/12

Expected recruitment end date

2019-01-02, 1397/10/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of the effect of oral liquid therapy with intravenous fluid therapy on the adequacy of renal function after angiography and angioplasty

Public title

Comparative study of the effect of oral liquid therapy with intravenous fluid therapy on the adequacy of renal function after Angiography and Angioplasty

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with EF more than 35%. Creatinine is less than 1.5. Patients who do not have ESRD and do not undergo dialysis. Patients with stable hemodynamic status and blood pressure greater than 90mmHg. The calculated GFR values are above 30 CC / min / 1.73. Older people are 18 years of age and under 70 years of age.

Exclusion criteria:

People who have gastrointestinal illness after consulting a gastroenterologist Patients with kidney problems Patients taking medications that are effective in kidney function.

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Not randomized

Randomization description

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 Sabzevar University of Medical Sciences

Street address

Central Organization of Medical Sciences,Asad Abadi Street , Sabzevar, Khorasan Razavi, Iran

City

Sabzevar

Province

Razavi Khorasan

Postal code

9617913112

Approval date

2018-11-21, 1397/08/30

Ethics committee reference number

IR.MEDSAB.REC.1397.066

Health conditions studied

1

Description of health condition studied

angiography

ICD-10 code

XVIII

ICD-10 code description

Symptoms, signs and abnormal clinical and laboratory findings, not elsewhere classified

2

Description of health condition studied

Angioplasty

ICD-10 code

XVIII

ICD-10 code description

Symptoms, signs and abnormal clinical and laboratory findings, not elsewhere classified

Primary outcomes

1

Description

Changes in creatinine before, after angiography, with an increase in cr content of more than 25% of baseline, or more than 0.5 mg / dl of creatinine increase, is considered as an incidence of CIN.

Timepoint

Blood creatinine measurements at the beginning of the study (before the intervention) and 48 hours after the intervention

Method of measurement

The blood creatinine test carried out by the Bt4500 device.

2

Description

Level Of GFR

Timepoint

Before Of Intervention And 48 hours after intervention

Method of measurement

Due to the formula * Cockcroft-Gault

3

Description
Level Of EF
Timepoint
Before Of Intervention
Method of measurement
With an electrocardiograph device

4

Description
Kidney function adequacy
Timepoint
48 hours after intervention
Method of measurement
GFR evaluation

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:Oral fluid therapy in patients undergoing angiography and angioplasty
Category
Prevention

2

Description
Control group:Venous fluid therapy in patients undergoing angiography and angioplasty
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Heshmatieyeh Hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
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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
Sabzevar 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
Sabzevar University of Medical Sciences
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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