Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of Preventive Effect of Intravenous Trans Sodium Crocetinate on Contrast-Induced Nephropathy in Patients Undergoing Coronary Angioplasty : A randomized placebo-controlled triple-blind clinical trail

Protocol summary

Study aim

Determining effect of TSC in preventing ARF in patients undergoing elective coronary angioplasty

Design

triple-blind randomized clinical trial. In this phase 2 trial with a sample size of 152 outpatients, angioplasty candidates and randomized by site www.randomization.com

Settings and conduct

152 outpatients are candidates for angioplasty based on inclusion and exclusion criteria. checklist is filled out for the patient. Group 1: Patients undergoing elective angioplasty , receive TSC before angioplasty in addition to the standard measure of preventing kidney damage, and then on days 0 to 5 of the patient intervention in the form of oral crocetin tablets at a dose of 7.5 mg TID for 5 days group 2: in addition, they receive placebo vials before angioplasty, in following 5 days, they take placebo tablets TID Blood, urinary and clinical factors are measured during the study

Participants/Inclusion and exclusion criteria

Inclusion : Patients 18 years and older who are candidates for non-emergency angioplasty GFR <60 ml / min before angioplasty Mehran score > 11 consent to study receiving ARB or ACEI with statins do not have more than 15% difference in serum creatinine during the last three days intravenous hydration at least 4 hours before angioplasty Do not require emergency angiography in the first 48 hours Have no history of acute renal failure in the last 6 months or kidney transplantation Exclusion : dialysis before angiography other diseases leading to ARF active tumor exposure to intravenous contrast agents in the last 14 days heart failure taking special drugs

Intervention groups

control group receives standard interventions for ARF prevention, treatment group also receive TSC .

Main outcome variables

Primary outcome: effect of TSC on the occurrence of ARF Secondary outcome: Effect of TSC administration on ClCr, serum and BUN , cystatin C , Hs-CRP, 24-h urine, Mehran score, MDA

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20081019001369N8**
Registration date: **2022-04-14, 1401/01/25**
Registration timing: **registered_while_recruiting**

Last update: **2022-04-14, 1401/01/25**
Update count: **0**

Registration date

2022-04-14, 1401/01/25

Registrant information

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Hossein Hosseinzadeh

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-04, 1401/01/15

Expected recruitment end date

2022-11-22, 1401/09/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of Preventive Effect of Intravenous Trans Sodium Crocetinate on Contrast-Induced Nephropathy in Patients Undergoing Coronary Angioplasty : A randomized placebo-controlled triple-blind clinical trail

Public title
Evaluation of Preventive Effect of Intravenous Trans Sodium Crocetinate on Contrast-Induced Nephropathy
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Candidates for outpatient angioplasty
Exclusion criteria:
The presence of ESRD requires dialysis before angiography Presence of underlying diseases leading to acute renal failure regardless of contrast-induced acute renal failure Existence of active tumor History of exposure to intravenous contrast agents in the last 14 days for other reasons Existence of heart failure or cardiogenic shock Taking drugs interacting kidney function
Age
From **18 years** old
Gender
Both

Phase
2
Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **152**
More than 1 sample in each individual
Number of samples in each individual: **16**
One trans-sodium injectable vial of crostinate per person and three crocetin tablets per day for 5 days
Randomization (investigator's opinion)
Randomized
Randomization description
block randomization complete by using www.randomization.com. each block has 4 members defining as [AABB], [ABAB], [ABBA], [BABA], [BBAA], [BAAB]. Codes A and B are randomly assigned to the intervention groups and the control group. The aforementioned site selects 38 blocks at random from the four blocks so that 76 patients can be included in the study. patients will be assigned to one of the control groups according to the time of admission and at the beginning of admission according to the sequence obtained in the randomization stage. Interventions are allocated. These codes are not provided to the researcher present in the physician's office. Medications are also given to patient by number (A or B) and he is completely unaware of which drug or placebo is. The researcher's telephone number is also available for patients to call whenever any problem arises. (This researcher is not involved in prescribing or analyzing the data; however, he or she is solely responsible for evaluating and maintaining the codes and providing medication to patients based on a random code determined by the physician). The code assigned by him is recorded in the CRF form.
Blinding (investigator's opinion)
Triple blinded
Blinding description
After the codes are prepared and given to the researcher, if the inclusion criteria are met and based on the codes, the patient is randomly placed in one of the groups. The relevant code is recorded in the CRF form and the researcher considers the drug or placebo based on the assigned code for the patient. After the patient is admitted to the hospital, the patient is introduced to a nurse and the medication is prescribed by the nurse (therapist). Knows only the assigned code, performs the relevant evaluations, and after registration, the results are given to the person who performs the data analysis, in the form of a code, and the data analysis is performed without the knowledge of the data analyzer. And all confidential information is recorded and stored without mentioning the patient's name. The vials of medicine and placebo, as well as the pills taken, have a similar shape.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
کمیته منطقه ای اخلاق دانشگاه علوم پزشکی مشهد
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Blv.Vakilabad 2- School of Pharmacy-1365-91775
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Approval date
2022-01-01, 1400/10/11
Ethics committee reference number
IR.MUMS.REC.1400.308

Health conditions studied

1

Description of health condition studied
Certain current complications following acute myocardial infarction
ICD-10 code
I23
ICD-10 code description
Certain current complications following ST elevation (STEMI) and non-ST elevation (NSTEMI) myocardial infarction (within the 28 day period)

Primary outcomes

1

Description
effect of TSC on the occurrence of acute kidney injury
Timepoint
during 5 days
Method of measurement
mehran score

Secondary outcomes

1

Description
effect of TSC administration on creatinine clearance level
Timepoint
days 0 , 1 , 2 ,5
Method of measurement
laboratory evaluation

2

Description
effect of TSC administration on serum creatinine and BUN level
Timepoint
days 0 , 1 , 2 ,5
Method of measurement
laboratory evaluation

3

Description
effect of TSC administration on cystatin C level
Timepoint
days 0 , 1 , 2
Method of measurement
laboratory evaluation

4

Description
effect of TSC administration on hs-CRP level
Timepoint
days 0 , 5
Method of measurement
laboratory evaluation

5

Description
effect of TSC administration on 24hours urine analysis test
Timepoint
days 0 , 1 , 2 ,5
Method of measurement
laboratory evaluation

6

Description
effect of TSC administration on mehran score
Timepoint
days 0 , 5
Method of measurement
laboratory evaluation

7

Description
effect of TSC administration on MDA test
Timepoint
days 0 , 5
Method of measurement
laboratory evaluation

Intervention groups

1

Description
Intervention group: Patients undergoing elective angioplasty who, in addition to the standard preventive measure of CIN, recieve TSC at dose of 0.5 mg / kg as an injection, 5 minutes before angioplasty, and then on days 0 to 5 of the patient intervention in the form of oral tablets of crocetin 7.5 mg daily 3 tablets for 5 days
Category
Treatment - Drugs

2

Description
Control group: Patients undergoing elective angioplasty who, in addition to the standard preventive measure of CIN , placebo vial containing normal saline They receive 0.9% at a dose of 0.5 mg / kg by injection 5 minutes before angioplasty, and then on days 0 to 5 of the intervention, the patient takes oral placebo tablets for 5 days, 3 tablets daily.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Reza Hospital
Full name of responsible person
Arash gholoobi
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Sponsors / Funding sources

1

Sponsor
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https://v-research.mums.ac.ir/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
arash gholoobi
Position
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Person responsible for updating data

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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
Not applicable