Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 May 2026

Evaluation of the Effect of Crocin on Oxidative Stress Biomarkers in Patients under Angiography with Contrast Agents: A Randomized Controlled Clinical Trial

Protocol summary

Study aim

determination of the effect of crocin on oxidative Stress biomarkers in patients under Angiography with Contrast Agents

Design

A randomized clinical trial with the control group, with parallel, randomized groups, phase 2 per 100 patients, rand function was used using Excel stratified random blocks method.

Settings and conduct

This study will be performed at Ayatollah Madani Hospital in Khorramabad, all patients in the intervention and control groups will receive 1ml/kg normal saline from 6 hours before to 6 hours after receiving Iodixanol. In addition to hydration, the intervention group will receive 30 mg crocin orally from the night before to the second night after angiography. The baseline level of the biomarkers (superoxide dismutase, malondialdehyde, catalase, glutathione peroxidase, reactive oxygen species), before the intervention, and to four hours after receiving contrast medium will be evaluated.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patient consent; older than18 years old; systolic blood pressure of greater than 90 mm Hg Exclusion criteria: patient's tendency to exit from the study; the impossibility of intravenous hydration، participate in other clinical interventions over the past twenty-eight days; history of hypersensitivity to contrast media and saffron

Intervention groups

Control group: all patients will receive 1ml/kg normal saline from 6 hours before to 6 hours after receiving Iodixanol. Intervention group: In addition to hydration, the intervention group will receive 30 mg crocin (Sami Saz Pharmaceutical Company) orally from the night before to the second night after angiography.

Main outcome variables

superoxide dismutase, malondialdehyde, catalase, glutathione peroxidase, reactive oxygen species, serum creatinine, and blood urea nitrogen

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200721048159N5**
Registration date: **2021-12-29, 1400/10/08**
Registration timing: **retrospective**

Last update: **2021-12-29, 1400/10/08**
Update count: **0**

Registration date

2021-12-29, 1400/10/08

Registrant information

Name

Forouzan Ahmadpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 66 3312 0239

Email address

ahmadpoor.f@lums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-22, 1400/06/31

Expected recruitment end date

2021-12-27, 1400/10/06

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the Effect of Crocin on Oxidative Stress Biomarkers in Patients under Angiography with Contrast Agents: A Randomized Controlled Clinical Trial

Public title
Antioxidant effects of crocin in patients undergoing angiography
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
patient consent to enter to the study being candidate for angiography being over 18 years old systolic pressure of greater than 90 mm Hg
Exclusion criteria:
patient's tendency to exit from the study having Anaphylactic and anaphylactoid reactions during contrast media administration consumption of common antioxidant medicines in less than one week before use of contrast media and angiography consumption of nephrotoxic medicines (aminoglycosides, vancomycin and others) in less than one week before use of contrast media and angiography unstable kidney status or need of kidney transplantation impossibility of intravenous hydration for the patient consumption of Warfarin pregnancy and breastfeeding history of hypersensitivity to saffron history of hypersensitivity to contrast media participate in other clinical trials that their results may confound this intervention at least for a 28 days period
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be divided into two groups using the stratified blocked randomization method. In this way, considering the gender (female, male), a stratum will be formed and within this stratum, the samples in the form of four blocks will be randomly assigned to the desired groups.
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 Committe of Lorestan University of Medical Sciences
Street address
Office of Research Ethics Committee, Vice Chancellor for Research and Technology, Lorestan University of Medical Sciences, 3 km of Khorramabad-Tehran Road, Pardis University Complex, Khorramabad, Lorestan
City
Khorramabd
Province
Lorestan
Postal code
381251698
Approval date
2021-08-17, 1400/05/26
Ethics committee reference number
IR.LUMS.REC.1400.122

Health conditions studied

1

Description of health condition studied
contrast induced acute kidney Injury
ICD-10 code
N17.8
ICD-10 code description
Other acute kidney failure

Primary outcomes

1

Description
serum creatinine
Timepoint
before getting medical regime and 24 and 48 hours after getting contrast media
Method of measurement
patient's medical file

2

Description
Blood urea nitrogen
Timepoint
Before getting medical regime and 24 and 48 hours after getting contrast media
Method of measurement
Laboratory kit

3

Description
Superoxide dismutase
Timepoint
Zero hours before getting medical regime of study and 4 hours after getting contrast media
Method of measurement
Laboratory kit

4

Description
Malondialdehyde
Timepoint
Zero hours before getting medical regime of study and 4 hours after getting contrast media
Method of measurement
Laboratory kit

5

Description
Catalase
Timepoint
Zero hours before getting medical regime of study and 4 hours after getting contrast media
Method of measurement
Laboratory kit

6

Description
Glutathione proxidase
Timepoint
Zero hours before getting medical regime of study and 4 hours after getting contrast media
Method of measurement
Laboratory kit

7

Description
Reactive oxygen species
Timepoint
Zero hours before getting medical regime of study and 4 hours after getting contrast media
Method of measurement
Laboratory kit

Secondary outcomes

empty

Intervention groups

1

Description
Control group: normal saline 1ml/kg from 6 hours before to 6 hours after administration of contrast agent
Category
Prevention

2

Description
Intervention group: normal saline 1ml/kg from 6 hours before to 6 hours after administration of contrast agent + 30mg/day crocina (Two tablets containing 15 mg of purified crocin from Poyesh Sina Pharmaceutical Company) form the night before receiving contrast agent to the second night after reviving contrast agent
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Ayatullah Madani Hospital
Full name of responsible person
Forouzan Ahmadpour
Street address
Shahid Ayatullah Madani Hospital, Khairabad Street, Shaghayegh Square, Khorramabad, Lorestan
City
Khorramabad
Province
Lorestan
Postal code
6814713115
Phone
+98 66 3341 9123
Fax
+98 66 3343 7164
Email
ahmadpourforoz@yahoo.com
Web page address
http://madani.lums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research and Technology of Lorestan University of Medical Sciences
Full name of responsible person
Ebrahim Falahi
Street address
Vice Chancellor for Research and Technology, Lorestan University of Medical Sciences, 3 km of Khorramabad-Tehran Road, Pardis University Complex, Khorramabad, Lorestan
City
Khorramabad
Province
Lorestan
Postal code
6813833946
Phone
+98 66 3330 2033

Email
international@lums.ac.ir
Web page address
http://en.lums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for Research and Technology of Lorestan 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
Khoram-Abad University of Medical Sciences
Full name of responsible person
Forouzan Ahmadpour
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Medical Pharmacy
Street address
Shahid Ayatullah Madani Hospital, Khairabad Street, Shaghayegh Square, Khorramabad, Lorestan
City
Khorramabad
Province
Lorestan
Postal code
6814713115
Phone
+98 66 3341 9123
Fax
+98 66 3343 7164
Email
ahmadpourforoz@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Khoram-Abad University of Medical Sciences
Full name of responsible person
Forouzan Ahmadpour
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Medical Pharmacy
Street address
Faculty of Pharmacy, Lorestan University of Medical Sciences, , 3 km of Khorramabad-Tehran Road, Pardis University Complex, Khorramabad, Lorestan
City
Khorramabad
Province
Lorestan
Postal code
6814713115
Phone
+98 66 3341 9123
Fax
+98 66 3343 7164
Email
ahmadpourforoz@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Khoram-Abad University of Medical Sciences
Full name of responsible person
Forouzan Ahmadpour
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Medical Pharmacy
Street address
Faculty of Pharmacy, Lorestan University of Medical Sciences, , 3 km of Khorramabad-Tehran Road, Pardis University Complex, Khorramabad, Lorestan
City
Khorramabad
Province
Lorestan
Postal code
6814713115
Phone
+98 66 3341 9123
Fax
+98 66 3343 7164
Email
ahmadpourforoz@yahoo.com

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