

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 than 18 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

ahmadpour.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 Committee 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 peroxidase

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

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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

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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
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

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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

Undecided - It is not yet known if there will be a plan to make this available