Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Evaluation of Terminalia chebula extract in preventing contrast media-induced nephrotoxicity

Protocol summary

Study aim
1. Determination of mean serum creatinine levels in the intervention and control groups on day zero (before treatment) and 72 hours after treatment 2. Determination of mean BUN levels in the intervention and control groups on day zero (before treatment) and 72 hours after treatment 3. Determination of mean urine output in the intervention and control groups on day zero (before treatment) and 72 hours after treatment

Design
Randomized controlled clinical trial

Settings and conduct
Hospitals affiliated to Isfahan University of Medical Sciences, Al-Zahra, Khurshid and Chamran hospitals

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1. Age over 18 years 2. Receiving iodine-containing laxatives 3. eGFR over 60 (using the CKD-EPI formula) Exclusion criteria: 1. Age over 65 years 2. Concomitant intake of other nephrotoxic drugs (such as vancomycin, aminoglycosides, amphotericin-B, colistin, cisplatin, calcineurin inhibitors) 3. Failure to complete the study by the end of the third day 4. Pregnancy and lactation

Intervention groups
For the case group, 1000 mg of Helilah extract (two capsules) will be administered every 12 hours, starting 6 hours before the patient is injected with contrast material and continuing for 3 days until the patient has completely eliminated the contrast material. The control group will receive only the usual ward protocol, which includes hydration.

Main outcome variables
In this study, changes in Cr, BUN, eGFR, and urinary output are examined as primary outcomes and the incidence of acute renal failure as secondary outcomes

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160713028901N8**
Registration date: **2026-06-22, 1405/04/01**
Registration timing: **prospective**

Last update: **2026-06-22, 1405/04/01**
Update count: **0**

Registration date
2026-06-22, 1405/04/01

Registrant information

Name
Shirinsadat Badri

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 3792 7068

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badri@pharm.mui.ac.ir

Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-07-23, 1405/05/01

Expected recruitment end date
2027-07-22, 1406/04/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of Terminalia chebula extract in preventing contrast media-induced nephrotoxicity

Public title
Terminalia chebula extract in preventing nephrotoxicity
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Age over 18 years Received iodinated contrast agent eGFR over 60 (using CKD-EPI formula)
Exclusion criteria:
Age over 65 years Concomitant administration of other nephrotoxic drugs (e.g. vancomycin, aminoglycosides, amphotericin-B, colistin, cisplatin, calcineurin inhibitors) Failure to complete the study by the end of the third day Pregnancy and lactation
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **86**
Randomization (investigator's opinion)
Randomized
Randomization description
Random sequence generation will be performed using block randomization with variable block sizes. The randomization sequence will be generated using the Randomization.com software. Block sizes will vary randomly between 6 and 9 to prevent predictability of allocation. The sequences will be placed in sealed, numbered envelopes, and treatment allocation will be determined based on the order of patient enrollment.
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
Research Ethics Committee of the Faculties of Pharmacy and Nutrition -Isfahan University of Medical
Street address
Isfahan University of Medical Sciences and Health Services, Hezar Jarib St.
City
Isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2026-04-05, 1405/01/16
Ethics committee reference number
IR.MUI.PHANUT.REC.1405.006

Health conditions studied

1

Description of health condition studied
Nephrotoxicity
ICD-10 code
N17.9
ICD-10 code description
Acute kidney failure, unspecified

Primary outcomes

1

Description
eGFR changes
Timepoint
At baseline and at the end of treatment (after 72 hours)
Method of measurement
Calculation with the CKD-EPI formula

2

Description
changes in creatinine serum level
Timepoint
At baseline and at the end of treatment (after 72 hours)
Method of measurement
measuring creatinine level in serum sample

3

Description
changes in BUN level
Timepoint
At baseline and at the end of treatment (after 72 hours)
Method of measurement
measuring BUN level in blood sample

4

Description
changes in urine output
Timepoint
At baseline and at the end of treatment (after 72 hours)
Method of measurement
measuring urine volume

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: All patients will be hydrated before receiving the contrast agent according to the center's guidelines and protocol, as 1 mL/kg/hour of normal saline for 6 to 12 hours before receiving the contrast agent and 1 mL/kg/hour of normal saline for 6 to 12 hours during and after receiving the contrast agent. For the intervention group, 1000 mg of Helilah extract (two capsules) every 12 hours, starting 6 hours before the contrast agent injection for the patient and continuing for 3 days until the contrast agent is completely excreted from the patient.

Category
Prevention

2

Description
Control group: All patients will be hydrated before receiving the contrast agent according to the center's guidelines and protocol, as 1 mL/kg/hour of normal saline for 6 to 12 hours before receiving the contrast agent and 1 mL/kg/hour of normal saline for 6 to 12 hours during and after receiving the contrast agent. The control group will not receive any medication other than the center's standard protocol.

Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Al-Zahra hospital
Full name of responsible person
Shirin Sadat Badri
Street address
Al-Zahra hospital , Sofeh Boulevard, Shahid Keshvari Highway
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Isfahan
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2

Recruitment center
Name of recruitment center
Khorshid Hospital
Full name of responsible person
Shirin Sadat Badri
Street address
Khorshid Hospital, Ostandari Street
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Isfehan
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Email
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3

Recruitment center
Name of recruitment center
Chamran Hospital
Full name of responsible person
Shirin Sadat Badri
Street address
Chamran Hospital, Salman Farsi street
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Email
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Mehdi Asgari
Street address
Hezar jerib
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Isfahan
Province
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Postal code
8174673461
Phone
+98 31 3668 8064
Fax
Email
res@mui.ac.ir
Web page address
https://research.mui.ac.ir/fa
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source
Esfahan 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
Esfahan University of Medical Sciences

Full name of responsible person
Shirinsadat Badri

Position
Associate Professor

Latest degree
Specialist

Other areas of specialty/work
Medical Pharmacy

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Shirinsadat Badri

Position
Associate Professor

Latest degree
Specialist

Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity
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Associate Professor

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Initially, both inpatients and outpatients will be included in the study; medication will be administered in the hospital for inpatients and at home for outpatients. In both groups of patients, if testing and follow-up are not possible by the third day, the patient will be excluded from the study. As mentioned in the objectives, urine output will be measured only in inpatients.

When the data will become available and for how long
The start of the data access period will be in October 2027, after the defense of the thesis and the publication of the article resulting from the project.

To whom data/document is available

Researchers, students and teachers working in academic and medical institutions

Under which criteria data/document could be used

In order to design similar studies or use the results of this study for systematic review and meta-analysis of data

From where data/document is obtainable

Online scientific databases, including PubMed, Web of Science, Scopus, and... Website of Central Library of Isfahan University of Medical Sciences, address: https://diglib.mui.ac.ir/ or by sending an email to the corresponding author: badri@pharm.mui.ac.ir

What processes are involved for a request to access data/document

Searching with keywords in scientific internet databases, Search through the title of the project on the website of the digital library of Isfahan University of Medical Sciences. Internet search on the website of the magazine where the article from the project is published

Comments