Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluating the effectiveness of Silymarin on the prevention of gentamicin nephrotoxicity in hospitalized patients at Imam Reza & Vali-Asr hospitals in Birjand

Protocol summary

Study aim

Determine the efficiency of silymarin in the prevention of gentamicin-induced nephrotoxicity in patients hospitalized in Imam Reza and Vali-Asr hosptals in Mashhad, Iran

Design

A clinical trial was conducted in two groups of control and treatment groups, double blind, randomized with permutable blocking method

Settings and conduct

Multi-center, randomized, double-blind, placebo-controlled clinical trials in two educational centers affiliated to Birjand University of Medical Sciences including Imam Reza Hospital and Vali-e-Asr Hospitals

Participants/Inclusion and exclusion criteria

Patients referring to educational hospitals of Birjand University of Medical Sciences who have been diagnosed with systemic gentamicin for at least 7 days with the following conditions: The patient's hemodynamic stability; the desire to participate in the study; gentamicin is given intravenously or intramuscularly for at least 1 week; no history of confirmed acute kidney injury; no history of confirmed chronic kidney injury; no use of gentamicin by intravenous or muscle in the past 14 days; no history of confirmed allergic reactions following oral administration of silymarin; no history of confirmed allergic reactions following oral administration of silymarin; do not receive medications or antioxidant compounds; do not receive high-renal toxicity medicines at the same time; oral tolerance to medications.

Intervention groups

Two treatment groups and control. Gentamycin will be injected to patients in both groups based on the treatment protocol. However, in the patients in the treatment group, the Silymarin tablet of goldaru company (livergol) (140 mg three times daily) is prescribed orally and as long as the gentamicin is prescribed.

Main outcome variables

Determine the efficacy of silymarin in preventionof increase in serum gentamicin-induced creatinine levels, GFR reduction, ATN, and electrolyte imbalance caused by gentamicin

General information

Reason for update

Acronym

SNG

IRCT registration information

IRCT registration number: **IRCT20161010030246N3**
Registration date: **2018-11-21, 1397/08/30**
Registration timing: **registered_while_recruiting**

Last update: **2018-11-21, 1397/08/30**
Update count: **0**

Registration date

2018-11-21, 1397/08/30

Registrant information

Name
Iman Karimzadeh
Name of organization / entity
Shiraz University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-23, 1397/05/01

Expected recruitment end date

2019-07-23, 1398/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effectiveness of Silymarin on the prevention of gentamicin nephrotoxicity in hospitalized patients at Imam Reza & Vali-Asr hospitals in Birjand

Public title

Evaluating the effectiveness of Silymarin on the prevention of gentamicin nephrotoxicity

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

The patient's hemodynamic stability The desire to participate in the study Gentamicin is given intravenous or intramuscular for at least 1 week at a dose of 5 mg / kg / day or 80-100 mg / TDS No history of confirmed acute kidney injury. No history of confirmed chronic kidney injury. No use of gentamicin by intravenous or muscle in the past 14 days. No history of confirmed allergic reactions following oral administration of silymarin No history of confirmed allergic reactions following oral administration of silymarin Do not receive medications or antioxidant compounds such as vitamin C, vitamin E or vitamin A Do not receive high-renal toxicity medicines at the same time Oral tolerance to medications

Exclusion criteria:

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **60**

More than 1 sample in each individual

Number of samples in each individual: **6**

Sampling of urine and blood (5 ml) of patients will be give before starting the drug (day zero) and on days 1, 2, 3, 5 and 7, gentamicin treatment .

Randomization (investigator's opinion)

Randomized

Randomization description

Multi-center, random blocking permutations, double-blind, placebo-controlled clinical trials

Blinding (investigator's opinion)

Double blinded

Blinding description

Researcher does not know the drug that the patient gives,is a placebo or the main drug. On the other hand, the participant (the patient) is not aware of the fact that the drug given to him is the main drug or placebo.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Vice-Chancellor for Research, Shiraz University of Medical Sciences, Zand Blvd., Shiraz, Iran

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Shiraz

Province

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Postal code

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Approval date

2018-07-04, 1397/04/13

Ethics committee reference number

IR.SUMS.REC.1397.330

Health conditions studied

1

Description of health condition studied

Gentamicin-induced renal toxicity in hospitalized patients

ICD-10 code

A30-A49

ICD-10 code description

Other bacterial diseases

Primary outcomes

1

Description

Determination of the efficacy of silymarin in preventing renal toxicity due to gentamicin by measuring the malondialdehyde indicator, evaluation of thiol groups, isoprostane and deoxy guanosine, serum creatinine level, serum urea nitrogen, sodium, potassium and magnesium concentration, and calculating sodium, potassium, Magnesium and urea

Timepoint

Sampling from urine and blood (5 ml) of patients before starting the drug (day zero) and on days 1, 2, 3, 5 and 7,

treatment with gentamicin

Method of measurement

Measurement of serum and urine levels of electrolytes, urea and creatinine using an autoanalyzer and Isoprostane and desoxy Guanosine indicator will be performed using ELISA and Zell bio kit.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this group, as long as the gentamicin is prescribed, the tablet of silymarin is prescribed by the Goldaru company (Livergol) at an oral dose of 140 mg three times daily.

Category

Prevention

2

Description

Control group: in this group patients with gentamicin will receive placebo 140 mg three times a day orally.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza & Vali-Asr hospitals in Birjand

Full name of responsible person

Iman Karimzadeh

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Roknabad, Shiraz 5Km, Karafarin St., Faculty of Pharmacy

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

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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

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Iman Karimzadeh

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

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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
No - There is not 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