Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

Evaluating the effect of febuxostat drug administration compared to placebo in septic patients hospitalized in the intensive care unit

Protocol summary

Study aim
Evaluating the effect of febuxostat compared to placebo in improving inflammatory indices of septic patients hospitalized in the ICU

Design
Clinical trial with a control group, double-blind, randomized, on 40 patients. For randomization, the clinical trial randomization tool of https://ctrandomization.cancer.gov/ was used.

Settings and conduct
The purpose of this study is to investigate the effects of febuoxstat in patients with sepsis. This randomized controlled clinical trial is conducted as a double-blind and in the form of a pilot study in Tabriz Imam Reza Hospital on 40 participants aged 18 to 80 with sepsis who have filled out the informed consent form. At the beginning of the study, the demographic and clinical information of the patients is evaluated. 40 patients are randomly placed in 2 groups A and B (20 people in each group). Patients in groups A and B are treated with febuxostat 40 mg or placebo for 10 days.

Participants/Inclusion and exclusion criteria
Inclusion criteria: patients aged 18-80 years with a diagnosis of sepsis with CRP Over 50mg/L. Exclusion criteria: pregnancy, breastfeeding, simultaneous use of azathioprine or mercaptopurine or methotrexate, sensitivity to febuxostat or allopurinol, or severe liver failure class C (ALT >3×ULN and serum total bilirubin more than 2×ULN

Intervention groups
At the beginning of the study, the demographic and clinical information of the patients is evaluated. 40 patients were randomly assigned to 2 groups A and B (20 people in each group) and were treated with febuxostat 80 mg or its placebo, once a day for 10 days.

Main outcome variables
Interleukin 6 (IL-6) biomarker as primary outcome of laboratory findings including CRP, billirubin, Cr, BUN, CBC, LFT and SOFA Score, qSOFA score

General information

Reason for update
Applying changes such as the sampling day (from day 3 to day 4) and removing one of the primary variables due to the impossibility of preparing a kit for its measurement.

Acronym

IRCT registration information
IRCT registration number: **IRCT20230814059148N1**
Registration date: **2023-10-10, 1402/07/18**
Registration timing: **prospective**

Last update: **2025-01-02, 1403/10/13**
Update count: **3**

Registration date
2023-10-10, 1402/07/18

Registrant information

Name
Saman Chaparzade

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 41 3382 8154

Email address
chaparzade.sam@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-11-22, 1402/09/01

Expected recruitment end date
2025-03-20, 1403/12/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluating the effect of febuxostat drug administration compared to placebo in septic patients hospitalized in the intensive care unit

Public title
the effect of febuxostat in sepsis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Septic patients who are hospitalized in the intensive care unit
Exclusion criteria:
Patients taking Azathioprine, Mercaptopurine, or Methotrexate at the same time Patients with sensitivity to Febuxostat or Allopurinol or Lactose or any component of the formulation of these drugs Patients with severe liver failure class C (ALT >3×ULN and total serum bilirubin more than 2×ULN) Patients with malignancy Pregnant and lactating women

Age
From **18 years** old to **80 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Block randomization with 2/4/6 blocks Randomization Unit: Individual The sequence of all possible permutations of intervention and control is written in blocks 4 and 6 Randomization tool: Randomization list from Clinical Trial Randomization Tool website and Excel software

Blinding (investigator's opinion)
Double blinded

Blinding description
The patients, principal investigator (executive student), supervisor, and relevant nurse will be blinded. Help will be taken from another person to prepare the pockets containing medicine or placebo. Only the code for each patient will be written on the envelopes, and the presenters will not see the list of random numbers. The data will be finally analyzed and the decoding of the codes will be the analyst's responsibility.

Placebo
Used

Assignment
Parallel

Other design features
So far, this drug has not been used in septic patients with this therapeutic purpose and effectiveness, and the results of its clinical trial have not been found in the search for sources. The study was designed based on published animal studies.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tabriz University of Medical Sciences - Faculty of Pharmacy
Street address
Presidency, Department of Clinical Pharmacy, Faculty of Pharmacy, Campus of Tabriz University of Medical Sciences, Atar Nishaburi North, Golgasht avenue, Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
5166414766

Approval date
2023-08-13, 1402/05/22

Ethics committee reference number
IR.TBZMED.PHARMACY.REC.1402.012

Health conditions studied

1

Description of health condition studied
sepsis

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Interleukin 6 (IL-6) plasma level

Timepoint
Day 0 (before the start) and day 4 of the study

Method of measurement
ELISA kit for detection of interleukin 6 serum level

Secondary outcomes

1

Description
The state of organ failure in sepsis

Timepoint

Days 0, 3, 7, 10

Method of measurement

Sequential Organ Failure Assessment (SOFA) Score

Intervention groups

1

Description

Intervention group: Receive 80 mg febuxostat tablets for 10 days, one tablet daily

Category

Treatment - Drugs

2

Description

Control group: placebo

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Special care department of Imam Reza Tabriz Hospital

Full name of responsible person

Hadi Hamishekar

Street address

Imam Reza Educational and Medical Center, in front of the central organization of the University, Golgasht St., Tabriz

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imamreza@tbzmed.ac.ir

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Parviz Shahabi

Street address

Department of Clinical Pharmacy, Faculty of Pharmacy, Campus of Tabriz University of Medical Sciences, Atar Nishaburi North, Golgasht avenue, Tabriz

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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

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Saman Chaparzade

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific

inquiries

Contact

Name of organization / entity
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Position
Student

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A Level or less

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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