Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Single-dose bioequivalence studies of two febuxostat tablets in healthy volunteers

Protocol summary

Study aim

Administration of test (generic) and reference (brand) products to healthy subjects Comparison of bioavailability and pharmacokinetics of two products Evaluation of interchangeability of two products

Design

All subjects signed an informed consent form approved by the Shahid Beheshti Medical University. Subjects were randomly assigned to receive either test or reference product in each period. This study was a single-dose, randomized, and crossover. The 2 phases of study were separated by a 2 weeks washout period. After an overnight fast for 12 h, the volunteers received 80 mg of either formulation, taken with 200 mL of water. 5 mL of blood samples were obtained just before drug administration and at 0.25, 0.5, 0.75, 1, 1.5, 2, 3, 4, 6, 8, 10, 12, 14 and 24 hr after that. Drug plasma concentrations were analyzed using a sensitive and selective HPLC method with ultraviolet detector. Pharmacokinetic parameters were calculated and compared.

Settings and conduct

This study was a single-dose, randomized, and crossover. All subjects signed an informed consent and got information about the drug name and its adverse effects. In each period, the subject received either test or reference products with a wash-out period in between. The study was performed at School of Pharmacy, Shahid Beheshti Medical University.

Participants/Inclusion and exclusion criteria

age: 18-50 years healthy

Intervention groups

Receiving test product Receiving reference product

Main outcome variables

Maximum plasma concentration, time to reach maximum plasma concentration and area under plasma concentration curve are the variable parameters. The first two variables show rate and the last one reveals amount of absorption, respectively.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200705048005N1**
Registration date: **2021-02-09, 1399/11/21**
Registration timing: **retrospective**

Last update: **2021-02-09, 1399/11/21**
Update count: **0**

Registration date

2021-02-09, 1399/11/21

Registrant information

Name

Mahraz Osouli

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8820 0118

Email address

m_osouli@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-02, 1398/12/12

Expected recruitment end date

2020-03-31, 1399/01/12

Actual recruitment start date

2020-03-05, 1398/12/15

Actual recruitment end date

2020-05-04, 1399/02/15

Trial completion date

2020-07-05, 1399/04/15

Scientific title

Single-dose bioequivalence studies of two febuxostat tablets in healthy volunteers

Public title
bioequivalence of febuxostat
Purpose
Other
Inclusion/Exclusion criteria
Inclusion criteria:
Male volunteer Age: 18-50 year Healthyvolunteer
Exclusion criteria:
History of liver, kidney and cardiovascular diseases that can affect drug clearance from body Any medication prescribed in the last two weeks
Age
From **18 years** old to **50 years** old
Gender
Male

Phase
Bioequivalence
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **26**
Actual sample size reached: **24**
Randomization (investigator's opinion)
Randomized
Randomization description
In order to randomize, in this study, random allocation rule has been used. For this purpose, first a total sample size of the candidates who met the inclusion criteria was determined and then randomly assigned a number of 13 of them to the first group who use the test drug using the table of numbers. We assign the other 13 persons to the second group who receive the reference medicine. Then, in the second period, the group that received the test drug will receive the reference drug and the other group will receive the test drug
Blinding (investigator's opinion)
Double blinded
Blinding description
The study was performed in two periods. Each subject received either test or reference product in each period. Subjects and the physician did not inform about the administered type of the product in each period.
Placebo
Not used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
School of Pharmacy Nursing and Midwifery, Shahid Beheshti Medical University
Street address
Niayesh Highway, Valiasr Ave
City
Tehran
Province
Tehran
Postal code
6153- 14155
Approval date
2020-03-02, 1398/12/12
Ethics committee reference number
IR.SBMU.PHARMACY.REC.1398.299

Health conditions studied

1

Description of health condition studied
Healthy subjects
ICD-10 code
-
ICD-10 code description
-

Primary outcomes

1

Description
Plasma drug concentration
Timepoint
0.25 0.5 0.75 1 2 3 4 6 8 10 12 14 24
Method of measurement
HPLC method

Secondary outcomes

empty

Intervention groups

1

Description
Receiving test formulation (generic product) In this study, subjects received one febuxostat tablet in each period. In the first period of the study, half of subjects received one 80 mg tablet (product of Chemidaru company). Blood samples were collected during 24-hours after after drug administration. At predetermined time (14 time points) 5 mL blood samples were collected. After that drug concentration was analysed by HPLC method. Pharmacokinetic parameters were calculated and compared.
Category
Treatment - Drugs

2

Description
Receiving reference formulation (brand product) In this study, subjects received one febuxostat tablet in each period. In the first period of the study, half of subjects received one brand 80 mg tablet (pUloric). Blood samples were collected during 24-hours after after drug administration. After that drug concentration was analysed by HPLC method. Pharmacokinetic parameters were calculated and compared.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
School of Pharmacy, SBMU

Full name of responsible person
Azadeh Haeri

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
ChemiDaru Pharmaceutical Company

Full name of responsible person
Mahdi Bakhshayesh

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16575/361

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stock@chemidarou.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
ChemiDaru Pharmaceutical Company

Proportion provided by this source
100

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Industry

Person responsible for general inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Mahraz Osouli

Position
PharmD

Latest degree
Medical doctor

Other areas of specialty/work
Medical Pharmacy

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Person responsible for scientific inquiries

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Medical Pharmacy

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
the study was performed for marketing the generic form of the drug
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available