Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

In- Vivo Bioequivalence study of Sorafenib tablet 200 mg Actro Middle East with brand drug (NEXAVAR® 200 mg, Bayer, Germany) in Iranian healthy volunteers.

Protocol summary

Study aim
In- Vivo Bioequivalence study of Sorafenib tablet 200 mg Actro Middle East with brand drug (NEXAVAR® 200 mg, Bayer, Germany) in Iranian healthy volunteers.

Design
In-vivo bioequivalence study of Sorafenib tablet 200 mg Actro Middle East in compared with reference drug ((NEXAVAR® 200 mg, Bayer, Germany)). The single blind, Cross-over, two period, two groups (Intervention and control) and randomized (paper lottery randomization method) study with one week wash-out time.

Settings and conduct
This study is carried out in Simin Baspar Tayf Gostar Company located in Tabriz. The study population is 24 healthy Iranian volunteers.This study is a single blind study and by taking out the drugs from the existing packaging, the volunteers will not know the time of receiving the test drug and the brand. This study is a cross over study that is performed in two time periods of 72 hours with a one-week wash-out period.

Participants/Inclusion and exclusion criteria
Inclusion criteria: participants are between 18-60 years old, Normal body mass index (BMI in the range of 18-28) Non Inclusion criteria: smoking; Have a history of heart, kidney and liver disease, Pregnancy, Drug addiction

Intervention groups
Intervention group: Single dose Sorafenib tablet 200 mg Actro Pharmaceuticals. Control group: brand drugs (NEXAVAR® 200 mg, Bayer, Germany)

Main outcome variables
Plasma drug concentration

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200105046010N42**
Registration date: **2021-10-29, 1400/08/07**
Registration timing: **prospective**

Last update: **2021-10-29, 1400/08/07**
Update count: **0**

Registration date
2021-10-29, 1400/08/07

Registrant information

Name
Javad Shokri

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 41 3661 4125

Email address
shokri.j@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-11-01, 1400/08/10

Expected recruitment end date
2022-07-01, 1401/04/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
In- Vivo Bioequivalence study of Sorafenib tablet 200 mg Actro Middle East with brand drug (NEXAVAR® 200 mg,

Bayer, Germany) in Iranian healthy volunteers.

Public title
In-vivo Bioequivalence Test of Sorafenib tablets with brand drug (NEXAVAR® Bayer, Germany)
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
General health Body mass index between18-28 Informed consent Being at the age of 18-60 years old
Exclusion criteria:
Smoking A history of cardiovascular disease A history of liver & kidney disease Pregnancy Alcohol & Drug addiction Hypersensitivity to the drug
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
Bioequivalence
Groups that have been masked

- Participant

Sample size
Target sample size: **24**
Randomization (investigator's opinion)
Randomized
Randomization description
For this reason, A 24- person group will be selected and divided to two 12-person groups randomly. The names of all volunteers will be written on paper pieces and wrapped in aluminum foils. The first 12 papers will randomly be withdrawn from bottle will be selected as group A and others will be categorized in group B.
Blinding (investigator's opinion)
Single blinded
Blinding description
Candidates are not aware of receiving the test drug or brand one. In a one-blind study, information that could distort the test result is hidden from the candidates, but the person in charge of the test is aware of it. Iranian Sorafenib and Sorafenib Brand are removed from their packaging by the executor and placed in similar and coded cans. Volunteers will not be informed about receiving the brand or test drug.
Placebo
Not used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tabriz University of Medical Sciences
Street address
Third floor; Central building; Tabriz University of Medical Sciences; Dneshgah St.
City
Tabriz
Province
East Azarbaijan
Postal code
5166614766
Approval date
2021-08-02, 1400/05/11
Ethics committee reference number
IR.TBZMED.REC.1400.465

Health conditions studied

1

Description of health condition studied
Bio equivalence test
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Blood drug concentration
Timepoint
Sampling times in this study will be 0, 1, 2, 2:30, 3, 3:20, 3:40, 4, 4:20, 4: 40, 5, 6, 8, 10, 12, 24, 48, 72 hours after prescribing the tablet.
Method of measurement
High Performance Liquid Chromatography with tandem mass spectroscopy detector

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: they will receive one test drug tablet (Sorafenib tablet 200 mg produced by Actro Middle East Pharmaceuticals). Blood samples will be taken from the volunteers during 72 hours at the mentioned times after drug administration and the concentration of Sorafenib in blood samples will be measured by liquid chromatography with mass spectroscopy detector.
Category
Treatment - Other

2

Description
Control group: will receive one test drug table

(NEXAVAR® 200 mg, Bayer, Germany). Blood samples will be taken from the volunteers for 72 hours at the mentioned times after drug administration and the concentration of Sorafenib in blood samples will be measured by liquid chromatography with mass spectroscopy detector.

Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Simin Baspar Teyf Gostar Company
Full name of responsible person
Javad Shokri
Street address
No.48, Ferdos square
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5167874434
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+98 41 3384 2724
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Shokri.j@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Actro Middle East Pharmaceutical Co
Full name of responsible person
Sanaz Golbabaei
Street address
No 58, 6th St, Balouchestan St, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1446863914
Phone
+98 21 4431 9003
Email
info@actoverco.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Actro Middle East Pharmaceutical Co
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
Persons

Person responsible for general inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Javad Shokri
Position
Professor
Latest degree
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Other areas of specialty/work
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
These date are as secure between researcher and related industries

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
Yes - There is a plan to make this available

Title and more details about the data/document
Only protocol and methods of study are sharable

When the data will become available and for how long
Only protocol and methods of study are shareable.

To whom data/document is available
Pharmaceutical and medical sciences researchers

Under which criteria data/document could be used
Projects information's for any publications is not allowed.

From where data/document is obtainable
By email to the project manager (shokri.j@gmail.com)

What processes are involved for a request to access data/document
This information is confidential and is at the disposal of the project sponsor. Upon request, the information will be provided to the applicant by the contractor's email after the

Comments