Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jul 2026

Comparative bioequivalence study of Metformin 1000 mg F.C. Tablet of Pharma Chemie and Actoverco. in 24 healthy male under fasting

Protocol summary

Study aim
This study will be performed to compare the pharmacokinetics and invivo parameters of metformin 1000 mg Capsule formulation as a test product with NEURONTIN® capsule formulation as a reference product and to evaluate the biocompatibility of these two formulations.

Design
Randomized, single-dose, crossover comparative bioequivalence study of Metformin 1000 mg of Pharma Chemie and Actoverco in 24 healthy male under fasting.

Settings and conduct
In each period, volunteers will receive a single dose of the treatment in the Farabi Clinic (Eslamshahr, Tehran). 2 dosing periods will be separated by a 7-day washout period.

Participants/Inclusion and exclusion criteria
Healthy subjects (male) between 20 – 45 years of age and Body Mass Index (BMI) within 15% of normal range according to the accepted normal values between 18.5 and 30 (inclusive), calculated as kg/m2. Subjects with no significant diseases or clinically significant abnormal findings during screening, medical history, clinical examination and laboratory evaluations. History of allergy or intolerance to metformin or other similar acting agents. Any significant acute or chronic medical illness especially renal insufficiency (Estimated creatinine clearance (Clcr) of < 80ml/min using the Cockcroft Gault formula). Current or recent (within 3 months) gastrointestinal disease. Any major surgery within 4 weeks of study drug administration.

Intervention groups
ntervention group (test): Metformin 1000 mg Tablet, produced by Pharma Chemie is the test product. In each period, 12 of 24 subjects will be given a single oral dose of this product. Intervention group (Reference): Glucophage® capsule, produced by Actoverco is the reference product. In each period, 12 of 24 subjects will be given a single oral dose of this product.

Main outcome variables
Peak Plasma Concentration

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20180620040164N17**
Registration date: **2022-01-02, 1400/10/12**
Registration timing: **prospective**

Last update: **2022-01-02, 1400/10/12**
Update count: **0**

Registration date
2022-01-02, 1400/10/12

Registrant information

Name
Behzad Montaha Sangari

Name of organization / entity
Noor research and educational institute (Tavan)

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-01-21, 1400/11/01

Expected recruitment end date
2022-02-04, 1400/11/15

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative bioequivalence study of Metformin 1000 mg F.C. Tablet of Pharma Chemie and Actoverco. in 24 healthy male under fasting

Public title

Bioequivalence study of Metformin 1000 mg F.C. Tablet in 24 healthy male under fasting conditions

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Healthy subjects (male) between 20 – 45 years of age and Body Mass Index (BMI) within 15% of normal range according to the accepted normal values between 18.5 and 30 (inclusive), calculated as kg/m2. Subjects with no significant diseases or clinically significant abnormal findings during screening, medical history, clinical examination and laboratory evaluations. Subjects with normal vital signs. Subjects who agree with patient consent form.

Exclusion criteria:

History of allergy or intolerance to metformin or other similar acting agents. Any significant acute or chronic medical illness especially renal insufficiency (Estimated creatinine clearance (Clcr) of < 80ml/min using the Cockcroft Gault formula). Current or recent (within 3 months) gastrointestinal disease. Any major surgery within 4 weeks of study drug administration. Smoking more than 10 cigarettes per day and could not tolerate cigarette cessation during each clinical period. Subjects who has used any drug including prescription or Over-The-Counter (OTC) drugs within 7 days prior to the start of the study and might need drug intake during study period; History of alcohol or drug abuse within 2 years before the start of the study. Heavy drinker of caffeine, grapefruit juice or caffeinated drinks or who are on special diet (such as vegetarians) or do exertional physical activity. A history of difficulty with donating blood or donation of more than 500 ml blood within 7 days prior to the start of the study.

Age

From **20 years** old to **45 years** old

Gender

Male

Phase

Bioequivalence

Groups that have been masked

No information

Sample size

Target sample size: **26**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization schedule will be generated with the BEAR statistical software (Release V2.7.7). Each volunteer will be randomly assigned to one of the 2 different sequence of treatments according to the order of entering the study which will be allocated after screening.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Niayesh Highway, Valiasr Ave, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1996835113

Approval date

2021-11-02, 1400/08/11

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1400.203

Health conditions studied

1

Description of health condition studied

Bioequivalence investigation of the generic Pharma Chemie Metformin 1000 mg Tablet with brand Glucophage® Actoverco. Tablet.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Peak Plasma Concentration (Cmax)

Timepoint

During 2 months after intervention

Method of measurement

using non-compartmental model of Win-Nonlin Professional software version 3.2.A (Pharsight Corporation, USA)

Secondary outcomes

1

Description
AUC (Area Under the Concentration-Time Curve)
Timepoint
During 2 months after intervention
Method of measurement
using non-compartmental model of Win-Nonlin Professional software version 3.2.A (Pharsight Corporation, USA)

Intervention groups

1

Description
Intervention group: (test):Metformin 1000 mg Tablet, produced by Pharma Chemie is the test product. In each period, 12 of 24 subjects will be given single oral dose of this product.
Category
Treatment - Drugs

2

Description
Intervention group: Metformin 1000 mg Tablet, produced by Actoverco is the refrence product. In each period, 12 of 24 subjects will be given single oral dose of this product.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Hakim Farabi Clinic
Full name of responsible person
Ebrahim Siahpoosh
Street address
No. 57, Shemshad alley, Sallor city
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4635314588
Phone
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Email
mina.hasanabadi@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Pharma Chemie Pharmaceutical Co.
Full name of responsible person
Alireza Talaee
Street address
No 2 , 4th East Alley ,16th Street ,After Esteglal Town,Makhsous Karaj Road 8km, Tehran, Iran
City
Tehran
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Postal code
1459926609
Phone
+98 21 4452 5190
Email
info@pharmachemie.co
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Pharma Chemie 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
Industry

Person responsible for general inquiries

Contact
Name of organization / entity
Noor Research & Development Institute
Full name of responsible person
Ali Aghaei
Position
Master
Latest degree
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Person responsible for updating data

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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
It's not specified yet.
Study Protocol
Undecided - It is not yet known if there will be 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