Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparative bioequivalence study of Metformin 1000 mg E.R. Tablet of Dorsa Pharmaceutical Co and Merck

Protocol summary

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

Design
Non-blinded, randomized, crossover in vivo bioequivalence study in 24 healthy males under fasting conditions. Block randomization for a treatment sequence of Test/Reference or Reference/Test is used.

Settings and conduct
In each period, volunteers will receive a single dose of the treatment in the Noor Research and Development Institute (Tarasht, Tehran). 2 dosing periods will be separated by a 21-day washout period.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Healthy subjects (male) between 18 – 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. Exclusion Criteria: History of known sensitivity to the tested products Associated acute or chronic infections

Intervention groups
Intervention group (test): Metformin 1000 mg E.R. Tablet, produced by Dorsa Pharmaceutical Co. 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 Merckis 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: **IRCT20180620040164N67**
Registration date: **2024-06-23, 1403/04/03**
Registration timing: **prospective**

Last update: **2024-06-23, 1403/04/03**
Update count: **0**

Registration date
2024-06-23, 1403/04/03

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
2024-08-22, 1403/06/01

Expected recruitment end date
2024-09-05, 1403/06/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparative bioequivalence study of Metformin 1000 mg E.R. Tablet of Dorsa Pharmaceutical Co and Merck

Public title
Bioequivalence study of Metformin 1000 mg E.R. Tablet in 24 healthy male under fasting conditions

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Healthy subjects (male) between 18 – 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.

Exclusion criteria:
History of known sensitivity to the tested products Associated acute or chronic infections Blood pressure in standing position and after 5 minutes of rest, systole less than 90 or more than 140 mm Hg and diastole less than 50 or more than 90 mm Hg. Heart rate less than 50 or more than 90 beats per minute Abnormalities in ECG include (PR > 210 msec, QRS complex > 120 msec, QTcF > 430 msec) Smoking more than 10 cigarettes a day Loss of more than 500 ml of blood in less than 7 days.

Age
From **18 years** old to **45 years** old

Gender
Male

Phase
Bioequivalence

Groups that have been masked
No information

Sample size
Target sample size: **24**

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
2024-05-27, 1403/03/07

Ethics committee reference number
IR.SBMU.PHARMACY.REC.1403.038

Health conditions studied

1

Description of health condition studied
Diabetes mellitus

ICD-10 code
E08

ICD-10 code description
Diabetes mellitus due to underlying condition

Primary outcomes

1

Description
Peak Plasma Concentration (Cmax)

Timepoint
15 blood samples will be withdrawn pre-dose and at 1, 1.5, 2.5, 3, 4, 5, 6, 7, 8, 9, 10, 12, 24 and 48 hours 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
15 blood samples will be withdrawn pre-dose and at 1, 1.5, 2.5, 3, 4, 5, 6, 7, 8, 9, 10, 12, 24 and 48 hours 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 group1(test): Metformin 1000 mg E.R. Tablet, produced by Dorsa Pharmaceutical Co. 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 2 (refrence): Metformin 1000 mg E.R. Tablet, produced by Merck 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
Noor Research & Development Institute (Tavan)
Full name of responsible person
Behzad Montaha Sangari
Street address
Sharif Innovation Station, North Habibollah Street, Hosseini Square, Teymoury Street, Tarasht.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Dorsa Pharmaceutical Co.
Full name of responsible person
Amir Esmael Saghafinia
Street address
8th floor; -Fanavari Tarasht Tower; Teimori; Shahid Salehi Blvd
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Postal code
1459965204
Phone
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Email
info@dorsadarou.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Dorsa 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
Behzad Montaha Sangari
Position
CEO(Chef Executive Officer)
Latest degree
Medical doctor
Other areas of specialty/work
Medical Pharmacy
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Person responsible for scientific inquiries

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Position
Principal investigator
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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
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