

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

Comparative bioequivalence study of Glibenclamide 5mg tablet of Dorsa pharmaceutical Co. and Daonil 5 mg tablet of SANOFI as reference in 24 healthy male under fasting.

Protocol summary

Study aim

This study will be performed to compare the pharmacokinetics and in vivo parameters of Glibenclamide 5 mg tablet formulation as a test product with Daonil 5 mg tablet formulation as a reference product and to evaluate the bioequivalence of these two formulations.

Design

Non blinded, randomized, crossover in vivo bioequivalence study in 24 healthy male under fasting condition.

Settings and conduct

In each period, volunteers will receive a single dose intervention (1 or 2) in the Farabi Clinic (Eslamshahr, Tehran). 17 blood samples were collected during 72 hours post intervention. A 7-day washout interval separated to study periods.

Participants/Inclusion and exclusion criteria

Healthy subjects (male) between 20 - 45 years of age and Body Mass Index (BMI) within 15% of normal range between 18.5 - 30 kg/m². Subjects with no significant diseases or clinically significant abnormal findings during screening, medical history, clinical examination and laboratory evaluations. Subjects with known allergy to the products tested. Acute infection within one week before the first administration of the drug. Smoking more than 10 cigarettes per day and could not tolerate cigarette cessation during each clinical period.

Intervention groups

Intervention group 1: Glibenclamide 5 mg 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 2: Daonil 5 mg tablet, produced by SANOFI 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: **IRCT20180620040164N32**

Registration date: **2022-07-05, 1401/04/14**

Registration timing: **prospective**

Last update: **2022-07-05, 1401/04/14**

Update count: **0**

Registration date

2022-07-05, 1401/04/14

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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+98 21 6600 7026

Email address

info@tavaninstitute.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-10, 1401/06/19

Expected recruitment end date

2022-09-24, 1401/07/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparative bioequivalence study of Glibenclamide 5mg tablet of Dorsa pharmaceutical Co. and Daonil 5 mg tablet of SANOFI as reference in 24 healthy male under fasting.

Public title
Comparative in vivo evaluation of 2 Glibenclamide 5 mg Tablet formulations.

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 between 18.5 - 30 kg/m². Subjects with no significant diseases or clinically significant abnormal findings during screening, medical history, clinical examination and laboratory evaluations. Subjects that have normal vital signs. Subjects who agree with patient consent form.
Exclusion criteria:
Subjects with known allergy to the products tested. Acute infection within one week before the first administration of the drug. 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: **24**

Randomization (investigator's opinion)
Randomized

Randomization description
The randomization schedule will be generated with <https://www.sealedenvelope.com/simple-randomiser/v1/lis>. A 2*2 block randomization list is created. We have 12 blocks and within each two volunteer's number (allocated after screening) for all 24 volunteers. According to this list, a treatment sequence of Test/Reference or Reference/Test will be given to each volunteer.

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 School of Pharmacy and Nursing & Midwifery- Shahid Beheshti University of Medica

Street address

Niayesh Highway, Valiasr Ave, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1996835113

Approval date

2022-02-22, 1400/12/03

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1400.310

Health conditions studied

1

Description of health condition studied

Diabetes Mellitus

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

Primary outcomes

1

Description

Peak Plasma Concentration (Cmax)

Timepoint

17 blood samples will be withdrawn pre-dose and at 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 5, 6, 8, 9, 10, 12, 24, 48 and 72 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

17 blood samples will be withdrawn pre-dose and at 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 5, 6, 8, 9, 10, 12, 24, 48 and 72 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 group 1: Glibenclamide 5 mg 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. After 7-day wash-out period the intervention 2 will be given to these subjects.

Category

Treatment - Drugs

2

Description

Intervention group 2: Daonil 5 mg tablet, produced by SANOFI is the reference product. In each period, 12 of 24 subjects will be given single oral dose of this product. After 7-day wash-out period the intervention 1 will be given to these subjects.

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, in front of Sallor town.

City

Tehran

Province

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4635314588

Phone

+98 21 9253 5647

Email

partochem@gmail.com

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

City

Tehran

Province

Tehran

Postal code

1459965204

Phone

+98 21 5461 2000

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

Ali Aghaei

Position

Master

Latest degree

Master

Other areas of specialty/work

Pharmacy

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Sharif innovation station, North Habibollah Street, Hosseini Square, Teymouri Street, Tarasht

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Tavan Institute

Full name of responsible person
Seyed Mohsen Foroutan

Position
Principal investigator

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

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Person responsible for updating data

Contact

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Full name of responsible person

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Position
Master

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Pharmacy

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Email
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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