Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparative bioequivalence study of Telmisartan hydrochlorothiazide 80 / 12.5 mg Tablet of ActoverCo. and ®Micardisplus of Boehringer Ingelheim in 24 healthy subjects under fasting condition

Protocol summary

Study aim
This study will be performed to compare the pharmacokinetics and invivo parameters of Telmisartan hydrochloride 80 / 12.5 formulation as a test product with ®Micardisplus 80 / 12.5 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 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). Two dosing periods will be separated by a 7-day washout period.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Healthy subjects (male) between 18–55 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: Subjects with known allergy to the products tested; Smoking more than 10 cigarettes per day and could not tolerate cigarette cessation during each clinical period.

Intervention groups
Intervention group 1: Telmisartan hydrochloride 80 / 12.5 mg Tablet, produced by Actover 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: ®Micardisplus 80 / 12.5 mg Tablet, produced by Boehringer 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: **IRCT20180620040164N93**
Registration date: **2025-07-23, 1404/05/01**
Registration timing: **prospective**

Last update: **2025-07-23, 1404/05/01**
Update count: **0**

Registration date
2025-07-23, 1404/05/01

Registrant information

Name
Behzad Montaha Sangari

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

Country
Iran (Islamic Republic of)

Phone
+98 21 6600 7026

Email address
info@tavaninstitute.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-08-29, 1404/06/07

Expected recruitment end date
2025-09-12, 1404/06/21

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative bioequivalence study of Telmisartan hydrochlorothiazide 80 / 12.5 mg Tablet of ActoverCo. and ®Micardisplus of Boehringer Ingelheim in 24 healthy subjects under fasting condition

Public title

Comparative in vivo evaluation of 2 formulations of Telmisartan hydrochlorothiazide 80 / 12.5 mg Tablet

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Healthy subjects (male) between 18– 55 years of age. 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:

Subjects with known allergy to the products tested. Smoking more than 10 cigarettes per day and could not tolerate cigarette cessation during each clinical period. Subjects who has used any prescription or OTC drugs 14 days prior to the initiation of study and unable to refrain from the concomitant medications. History of alcohol or drug abuse. 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 **18 years** old to **55 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/lists. A 2*2 block randomization list is created. We have 12 blocks and within each two volunteer numbers (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,School of Pharmacy,Nursing&Midwifery-Shahid Beheshti University of medical sciences

Street address

Niayesh Highway, Valiasr Ave, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1996835113

Approval date

2025-07-21, 1404/04/30

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1404.102

Health conditions studied

1

Description of health condition studied

Adverse effect of other antihypertensive drugs, initial encounter

ICD-10 code

T46.5X5A

ICD-10 code description

Adverse effect of other antihypertensive drugs, initial encounter

Primary outcomes

1

Description

Peak Plasma Concentration (Cmax)

Timepoint

18 blood samples will be withdrawn pre-dose 0/25، 0/5، 0/75، 1، 1/25، 1/5، 1/75، 2/0، 2/5، 3، 4، 6، 8 ،11، 24، 48 و 72

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
18 blood samples will be withdrawn pre-dose 0/25، 0/5، 0/75، 1، 1/25، 1/5، 1/75، 2/0، 2/5، 3، 4، 6، 8 ،11، 24، 48 و 72
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: Telmisartan hydrochloride 80 / 12.5 mg F.C Tablet, produced by ActoverCo. is the test product. In each period, 12 of 24 subjects will be given a single oral dose of this product.
Category
Treatment - Drugs

2

Description
Intervention group:Telmisartan hydrochloride 80 / 12.5 mg F.C. Tablet, produced by Boehringer is the test product. In each period, 12 of 24 subjects will be given a 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.
City
Tehran
Province
Tehran
Postal code
1459926609
Phone
+98 21 6600 4027
Email
info@tavaninstitute.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Actoverco.
Full name of responsible person
Reza Karimi Mostofi
Street address
No. 58, 8th street, Gisha
City
Tehran
Province
Tehran
Postal code
3197996184
Phone
+98 21 4163 7000
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
Actoverco.
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 and educational institute (Tavan)
Full name of responsible person
Behzad Montaha Sangari
Position
CEO
Latest degree
Medical doctor
Other areas of specialty/work
Medical Pharmacy
Street address
Sharif innovation station, North Habibollah Street, Hosseini Square, Teymoury Street, Tarasht.Tehran
City
Tehran
Province
Tehran
Postal code
1459926609

Phone
+98 21 6600 7026
Fax
+98 21 6600 7026
Email
info@tavaninstitute.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Noor research and educational institute (Tavan)
Full name of responsible person
Mohsen Foroutan
Position
Principal investigator
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
Sharif innovation station, North Habibollah Street, Hosseini Square, Teymoury Street, Tarasht.Tehran
City
Tehran
Province
Tehran
Postal code
1459926609
Phone
+98 21 6600 7026
Fax
+98 21 6600 7026
Email
info@tavaninstitute.ir

Person responsible for updating data

Contact
Name of organization / entity
Noor research and educational institute (Tavan)
Full name of responsible person
Behzad Montaha Sangari
Position
CEO
Latest degree
Medical doctor
Other areas of specialty/work
Medical Pharmacy
Street address
Sharif innovation station, North Habibollah Street, Hosseini Square, Teymoury Street, Tarasht.Tehran
City
Tehran
Province
Tehran
Postal code
1459926609
Phone
+98 21 6600 7026
Fax
+98 21 6600 7026
Email
mina.hasanabadi@yahoo.com

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 undetermind yet.
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