Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparative bioequivalence study of Silymarin 210 mg Softgel of Gol Darou Pharmaceutical Co. and Silymarin 210 Hard Capsule of Gol Darou Pharmaceutical Co. in 24 healthy male under fasting

Protocol summary

Study aim

This study will be performed to compare the pharmacokinetics and invivo parameters of two different formulation of Silymarin 210 mg.

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 14-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: Silymarin 210mg Softgel, produced by Gol Darou Pharmaceutical Co. In each period, 12 of 24 subjects will be given a single oral dose of this product. Intervention group 2: Silymarin 210mg Hard capsule, produced by Gol Darou Pharmaceutical Co. 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: **IRCT20180620040164N88**
Registration date: **2025-05-14, 1404/02/24**
Registration timing: **prospective**

Last update: **2025-05-14, 1404/02/24**
Update count: **0**

Registration date

2025-05-14, 1404/02/24

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

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-06-09, 1404/03/19

Expected recruitment end date

2025-06-16, 1404/03/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparative bioequivalence study of Silymarin 210 mg Softgel of Gol Darou Pharmaceutical Co. and Silymarin 210 Hard Capsule of Gol Darou Pharmaceutical Co. in 24 healthy male under fasting

Public title
Comparative in vivo evaluation of 2 formulations of Silymarin 210 mg

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 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
Research Ethics Committees of School of Pharmacy and Nursing and Midwifery-Shahid Beheshti Universit

Street address
Niayesh Highway, Valiasr Ave, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1996835113

Approval date
2025-04-28, 1404/02/08

Ethics committee reference number
IR.SBMU.PHARMACY.REC.1404.010

Health conditions studied

1

Description of health condition studied
Poisoning by other drugs, medicaments and biological substances, accidental (unintentional)

ICD-10 code
T50.991

ICD-10 code description
Poisoning by other drugs, medicaments and biological substances, accidental (unintentional)

Primary outcomes

1

Description
Peak Plasma Concentration (Cmax)

Timepoint
18 blood samples will be withdrawn pre-dose and at 0, 0.25, 0.5, 0.75, 1, 1.33, 1.66, 2, 4, 6, 8, 11, 24

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
13 blood samples will be withdrawn pre-dose and at 0, 0.25, 0.5, 0.75, 1, 1.33, 1.66, 2, 4, 6, 8, 11, 24

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: Silymarin 210 mg softgel , produced by Gol Darou Pharmaceutical Co. In each period, 12 of 24 subjects will be given single oral dose of this product. After 14-day wash-out period the intervention 2 will be given to these subjects.
Category
Treatment - Drugs

2

Description
Intervention group: Silymarin 210 mg hard capsule , produced by Gol Darou Pharmaceutical Co. In each period, 12 of 24 subjects will be given single oral dose of this product. After 14-day wash-out period the intervention 2 will be given to these subjec
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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1459926609
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Gol Darou Pharmaceutical Co.
Full name of responsible person
Meysam Miran Rad
Street address
No. 47 [GPS], Soffeh Industrial Park, Km 7 of Shiraz Road, Isfahan(Routing)
City
Isfahan
Province
Isfehan
Postal code
8179135111
Phone
+98 31 3654 1370
Email
info@goldaruco.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Gol Darou 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 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
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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

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
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Position
CEO

Latest degree
Medical doctor

Other areas of specialty/work
Medical Pharmacy

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Behzad_first@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