Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Bioequivalence study of valproic acid 500mg sustained release tablet (Valpact) manufactured by Alborzzagros versus originator brand in healthy volunteers in the fasted condition

Protocol summary

Study aim

Bioequivalence Study of Valproic acid 500 mg sustained release tablet manufactured by Alborz zagos company versus originator brand (Depakine Chrono) manufactured by Sanofi company

Design

Bioequivalence study, crossover, single-blinded, 24 healthy volunteers. Simple randomization was used for randomization

Settings and conduct

The study is a single-blinded, cross-over and fasting, on two series of healthy volunteers. The study will be done in two periods (72h). The interval between these two periods is a week. In the first round of the study, the candidates were divided into two groups. the first group receives a test tablet and the second group receives a brand tablet. Blood samples are collected immediately before and after drug administration by volunteers. Then, drug extraction is done and samples are ready for analysis. These steps are performed in Radin laboratory in Tabriz

Participants/Inclusion and exclusion criteria

Inclusion criteria: General Health (Liver, Heart, and Kidney); Body Mass Index (18-28); Informed consent; age (18-55 years old). Exclusion criteria: smoking; history of cardiovascular disease; history of liver and kidney disease; alcohol and drug addiction; history of allergy to Valproic acid

Intervention groups

Intervention group 1: Depakine chrono 500mg as a reference Intervention group 2: Valpact 500 mg as a test

Main outcome variables

Maximum drug concentration; time to reach maximum drug concentration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200623047902N42**
Registration date: **2024-09-08, 1403/06/18**
Registration timing: **prospective**

Last update: **2024-09-08, 1403/06/18**
Update count: **0**

Registration date

2024-09-08, 1403/06/18

Registrant information

Name

Elham Ghasemian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6696 5196

Email address

ghasemian@zistdaru.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-10-21, 1403/07/30

Expected recruitment end date

2025-10-22, 1404/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Bioequivalence study of valproic acid 500mg sustained release tablet (Valpact) manufactured by Alborzzagros versus originator brand in healthy volunteers in the fasted condition

Public title
Bioequivalence study of valproic acid 500mg sustained release tablet

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
General Health (Liver, Heart, and Kidney) Body Mass Index (18-28) Informed consent Age (18-55 years old)

Exclusion criteria:
Smoking History of cardiovascular disease History of liver and kidney disease Alcohol and drug addiction History of allergy to Valproic acid

Age
From **18 years** old to **55 years** old

Gender
Both

Phase
Bioequivalence

Groups that have been masked

- Participant

Sample size
Target sample size: **24**
More than 1 sample in each individual
Number of samples in each individual: **42**
Blood sample

Randomization (investigator's opinion)
Randomized

Randomization description
People in the mentioned age group are invited to participate through the advertisement. People are then checked for health and healthy volunteers are identified. Each candidate is assigned a number from 1 to 24. The numbers are written on a plastic ball, poured into a container, and mixed. The balls are then removed randomly from the container. The first 12 no.s are considered as (first sequence: test medicine) and the second 12 no.s are considered as (second sequence: originator brand recipient). The volunteers don't have any information about taking the test or brand drug.

Blinding (investigator's opinion)
Single blinded

Blinding description
This study is a single-blinded clinical trial (volunteers). Test and Originator brand's tablets are removed from their packaging by the executor and placed in similar and coded cans. Volunteers will not be informed about receiving the brand or test dosage form

Placebo
Not used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committees of Tabriz University of Medical Sciences

Street address
Research and technology deputy,3rd floor, No 2 Central Building, Tabriz University of Medical Sciences, Golgasht Street

City
Tabriz

Province
East Azarbaijan

Postal code
5165665931

Approval date
2024-08-19, 1403/05/29

Ethics committee reference number
IR.TBZMED.REC.1403.428

Health conditions studied

1

Description of health condition studied
This study is performed on healthy volunteers and drug concentration in plasma is determined.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Drug concentration in plasma

Timepoint
0, 1, 2, 3, 4, 4.5, 5, 5.5, 6, 6.5, 7, 7.5, 8, 9, 10, 12, 15, 24, 36, 48, 72h after drug administration

Method of measurement
Liquid chromatography-MASS-MASS (LC- Mas/Mas)

Secondary outcomes

1

Description
Time to reach maximum drug concentration in plasma

Timepoint
After intervention

Method of measurement
The time to reach the maximum drug concentration is recorded.

2

Description
Extent of drug absorption
Timepoint
After intervention
Method of measurement
Calculation of area under curve of concentration -time

Intervention groups

1

Description
Intervention group: single dose, one oral tablet Depakine chrono 500mg manufactured by Sanofi as a reference product. after the washout period, the volunteers receive Valpact 500 mg tablet manufactured by Alborz zagros Co
Category
Treatment - Drugs

2

Description
Intervention group: single dose, one oral tablet Valpact 500mg manufactured by Alborzzagros company as a test product. after the washout period, the volunteers receive Depakine chrono 500 mg tablet manufactured by Sanofi Co
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Radin Laboratory
Full name of responsible person
Javad Shokri
Street address
No.22, first floor, Azadi alley, Moalem st., Abureihan St
City
Tabriz
Province
East Azarbaijan
Postal code
5154995671
Phone
+98 914 313 5843
Email
shokri.j@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Alborz Zagros company
Full name of responsible person
Amir Hossein Zolfaghari
Street address
No.58, 8th St. Kooye Nasr (Gisha St.)
City
Tehran
Province
Tehran
Postal code
1446863914
Phone
+98 21 4163 7000
Email
A.zolfaghari@alborzzagros.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Alborz Zagros company
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
Islamic Azad University
Full name of responsible person
Elham Ghasemian
Position
Visiting professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
Faculty of Pharmacy, Islamic Azad university of Damghan, Cheshme Ali bolivar, Saadi square
City
Damghan
Province
Semnan
Postal code
3671637856
Phone
+98 23 3522 5046
Fax
Email
Ghasemian_elham@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Islamic Azad University

Full name of responsible person
Elham Ghasemian

Position
Visiting professor

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

Street address
Faculty of Pharmacy, Islamic Azad university of Damghan, Cheshme Ali bolivar, Saadi square

City
Damghan

Province
Semnan

Postal code
3671637856

Phone
+98 23 3522 5046

Fax

Email
Ghasemian_elham@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Islamic Azad University

Full name of responsible person
Elham Ghasemian

Position
Visiting professor

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

Street address
Faculty of Pharmacy, Islamic Azad university of Damghan, Cheshme Ali bolivar, Saadi square

City
Damghan

Province
Semnan

Postal code
3671637856

Phone
+98 23 3522 5046

Fax

Email
Ghasemian_elham@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
These data are as secure between researchers and related industries.

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