Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jul 2026

Comparative bioequivalence study of Sodium Valproate 500 mg ER Tablet of Abian Pharmed and SANOFI Inc. in 24 healthy male under fasting conditions

Protocol summary

Study aim

This study will be performed to compare the pharmacokinetics and invivo parameters of Sodium Valproate 500 mg formulation as a test product with DEPAKINE® tablet formulation as a reference product and to evaluate the biocompatibility of these two formulations.

Design

Randomized, single-dose, crossover comparative bioequivalence study of Sodium Valproate 500 mg ER tablet of Abian Pharmed and SANOFI. in 24 healthy male under fasting.

Settings and conduct

In each period, volunteers will receive a single dose of the treatment in the Farabi Clinic (Eslamshahr, Tehran). 2 dosing periods will be separated by a 7-day washout period.

Participants/Inclusion and exclusion criteria

Healthy subjects (male) between 20 – 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. Subjects with normal vital signs. Subjects with known allergy to the products tested. History or presence of significant cardiovascular, pulmonary, hepatic, renal, gastrointestinal, endocrine, immunological, dermatological, neurological or psychiatric disease or disorder. History or presence of significant thyroid disease, adrenal dysfunction, organic intracranial lesion such as pituitary tumor.

Intervention groups

Intervention group (test): Sodium Valproate 500 mg ER Tablet, produced by Abian Pharmed is the test product. In each period, 12 of 24 subjects will be given a single oral dose of this product. Intervention group (Reference): DEPAKINE® 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: **IRCT20180620040164N14**
Registration date: **2021-11-18, 1400/08/27**
Registration timing: **retrospective**

Last update: **2021-11-18, 1400/08/27**
Update count: **0**

Registration date

2021-11-18, 1400/08/27

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

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-23, 1400/08/01

Expected recruitment end date
2021-11-06, 1400/08/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparative bioequivalence study of Sodium Valproate 500 mg ER Tablet of Abian Pharmed and SANOFI Inc. in 24 healthy male under fasting conditions

Public title
Bioequivalence study of Sodium Valproate 500 mg ER Tablet in 24 healthy male under fasting conditions
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 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. History or presence of significant cardiovascular, pulmonary, hepatic, renal, gastrointestinal, endocrine, immunological, dermatological, neurological or psychiatric disease or disorder. History or presence of significant thyroid disease, adrenal dysfunction, organic intracranial lesion such as pituitary tumor. Any treatment which could bring about induction or inhibition of hepatic microsomal enzyme system within 1 month of the study starting. 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 14 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: **26**
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'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 Shahid Beheshti University of Medical Sciences
Street address
Niayesh Highway, Valiasr Ave, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1996835113
Approval date
2021-09-21, 1400/06/30
Ethics committee reference number
IR.SBMU.PHARMACY.REC.1400.139

Health conditions studied

1

Description of health condition studied
Bioequivalence investigation of the generic Abian Pharmed. Sodium Valproate 500 mg ER Tablet with brand DEPAKINE® SANOFI Tablet.
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Peak Plasma Concentration (Cmax)

Timepoint
During 2 months 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
During 2 months 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: intervention group: (test): Sodium Valproate 500 mg ER Tablet, produced by Abian Pharmed 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: Intervention group: Sodium Valproate 500 mg ER Tablet, produced by SANOFI is the test 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
Hakim Farabi Clinic
Full name of responsible person
Ebrahim Siahpoosh
Street address
No. 57, Shemshad alley, Sallor city
City
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Province
Tehran
Postal code
4635314588
Phone
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Email
mina.hasanabadi@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Abian Pharmed Co.
Full name of responsible person
Sara Sepehr
Street address
No.273,Vahid Dastgerdi Street,Nelson Mandella Blvd.
City
Tehran
Province
Tehran
Postal code
1459926609
Phone
+98 21 8888 5154
Email
info@abiangroup.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Abian Pharmed 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
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Person responsible for scientific inquiries

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Other areas of specialty/work
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Person responsible for updating data

Contact
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Latest degree
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City
Tehran
Province
Tehran
Postal code
1459926609
Phone
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Email
info@tavaninstitute.ir

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 not specified yet
Study Protocol
Undecided - It is not yet known if there will be 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