Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jul 2026

A randomized, open label, single dose, crossover, bioequivalence study of Dimethyl Fumarate 240mg capsule of Nanoalvand Co., IRAN in comparison of Tecfidera 240mg capsule of Biogen in 24 healthy adult subjects under fasting condition

Protocol summary

Study aim

A randomized, open label, single dose, crossover, bioequivalence study of Dimethyl Fumarate 240mg capsule of Nanoalvand Co., IRAN in comparison of Tecfidera 240mg capsule of Biogen in 24 healthy adult subjects under fasting condition

Design

A randomized, open label, single dose, crossover, bioequivalence study in 24 healthy subjects under fasting condition

Settings and conduct

This study is carried out in Core Research Center of Zahedan University of Medical Sciences located in Imam Ali Hospital in Zahedan. There is a separate space for sampling and forecasting emergency situations in order to accommodate and rest the volunteers. This crossover and open label study was performed on 24 healthy volunteers. The volunteers' health is verified by the project physician prior to entry into the study, and the volunteers' status is regularly monitored by the project physician on the day of drug administration. This study will be covered by insurance in order to compensate for any adverse effects.

Participants/Inclusion and exclusion criteria

Main Inclusion criteria: Healthy subjects aged between 18 -50 years old and weighted between 50 – 100 kg\\ Main exclusion criteria: Clinically relevant deviations from normal; Donation a unit of blood or participated in another clinical trial within the last three

Intervention groups

Intervention: Dimethyl Fumarate 240mg capsule, produced by Nanoalvand Co., (IRAN), single dose. Control: Tecfidera one 240mg capsule, produced by Biogen company, single dose

Main outcome variables

Plasma concentration of Monomethyl Fumarate at 0 (before dosing), 0.5, 1.0, 1.5, 2.0, 2.5, 3.0, 3.5, 4.0, 4.5, 5.0, 6.0, 7.0, 8.0 & 10.0 hr. after dosing

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190706044111N22**
Registration date: **2021-07-03, 1400/04/12**
Registration timing: **prospective**

Last update: **2021-07-03, 1400/04/12**
Update count: **0**

Registration date

2021-07-03, 1400/04/12

Registrant information

Name

Ladan Tayebi

Name of organization / entity

Pars Biopharmacy Research Co.

Country

Iran (Islamic Republic of)

Phone

+98 21 8895 6061

Email address

l.tayebi@parsbiopharmacy.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-23, 1400/05/01

Expected recruitment end date

2022-03-20, 1400/12/29

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
A randomized, open label, single dose, crossover, bioequivalence study of Dimethyl Fumarate 240mg capsule of Nanoalvand Co., IRAN in comparison of Tecfidera 240mg capsule of Biogen in 24 healthy adult subjects under fasting condition

Public title
Bioequivalence study of Dimethyl Fumarate 240mg capsule of Nanoalvand Co., IRAN
Purpose
Other
Inclusion/Exclusion criteria
Inclusion criteria:
- Aged between 18 - 50 years - Body weight between 50 – 100 kg - Having good health on the basis of medical history and physical & clinical examination - Understand the procedures and give written informed consent
Exclusion criteria:
Subject had undergone surgery of the gastro-intestinal tract treatment. Subject had donated a unit of blood or participated in another clinical trial, within the last two months before the first Subject had a history of drug or alcohol abuse. Subject who smokes more than 10 cigarettes per day. Subject had used any prescription medication within 14 days, or any non-prescription medication within 7 days, before the first treatment.
Age
From **18 years** old to **50 years** old
Gender
Both

Phase
Bioequivalence
Groups that have been masked
No information
Sample size
Target sample size: **48**
More than 1 sample in each individual
Number of samples in each individual: **2**
Each volunteer, 2 times take medicine in the study. One-time test product and the other time reference product with at least one week wash-out period.
Randomization (investigator's opinion)
Randomized
Randomization description
Using Excel software, each subject will be randomly assigned to one of the two sequence AB or BA in a balanced manner
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 Zahedan University of medical Sciences
Street address
Dr. Hessabi square Zahedan University of Medical Sciences
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816743463
Approval date
2021-06-21, 1400/03/31
Ethics committee reference number
IR.ZAUMS.REC.1400.106

Health conditions studied

1

Description of health condition studied
Multiple Sclerosis (MS)
ICD-10 code
G35
ICD-10 code description
Multiple Sclerosis

Primary outcomes

1

Description
Monomethyl Fumarate (MMF)
Timepoint
at 0 (before dosing), 0.5, 1.0, 1.5, 2.0, 2.5, 3.0, 3.5, 4.0, 4.5, 5.0, 6.0, 7.0, 8.0 & 10.0 hr. after dosing
Method of measurement
Using High Performance Liquid Chromatography wit MS detector (HPLC/MS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Dimethyl Fumarate 240mg capsule,

produced by Nanoalvand Co., (IRAN), single dose.

Category
Other

2

Description
Control group: Tecfidera one 240mg capsule, produced by Biogen company, single dose.

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Core Research Lab. of ZAUMS

Full name of responsible person
Ghasemi Marzieh

Street address
Emam Ali Hospital, Salamat Blv., Khalij-e-Fars Highway

City
Zahedan

Province
Sistan-va-Balouchestan

Postal code
9816743111

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+98 54 3329 5664

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+98 54 3329 5665

Email
crl@zaums.ac.ir

Web page address
http://crl.zaums.ac.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Nanoalvand Co.

Full name of responsible person
Nima Sepehri

Street address
Unit 52, No. 485 Seyed Jamalledin-e-AsadAbadi st.

City
Tehran

Province
Tehran

Postal code
1439955991

Phone
+98 21 8802 0579

Fax
+98 21 8802 0597

Email
info@nanoalvand.com

Web page address
https://fa.nanoalvand.com/

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Nanoalvand 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
Persons

Person responsible for general inquiries

Contact

Name of organization / entity
Pars Biopharmacy Research Co.

Full name of responsible person
Ladan Tayebi

Position
Managing Director

Latest degree
Medical doctor

Other areas of specialty/work
Medical Pharmacy

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1st floor, Saeidi Dd end, Felestin Ave.

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Contact

Name of organization / entity
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Full name of responsible person
Ladan Tayebi

Position
Managing Director

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Person responsible for updating data

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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
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available