Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

A randomized, open label, two treatments, two periods, two sequence, single dose, crossover, bioequivalence study of Dexamethasone 4mg tablet of Abureihan Pharm Co., IRAN in comparison of Dexamethasone 4mg tablet of GALEN in 24 healthy adult subjects under fasting condition

Protocol summary

Study aim

- To assess the bioequivalence of test formulation (Dexamethasone 4mg tablet of Abureihan Pharm Co.) in comparison of reference product (Dexamethasone 4mg tablet of GALEN) by means of AUC0-t and Cmax, after single oral dose administration in healthy, adult subjects under fasting conditions

Design

A randomized, open label, two treatments, two periods, single dose, crossover, bioequivalence study of Dexamethasone 4mg tablet of Abureihan Pharm Co., IRAN in comparison of Dexamethasone 4mg tablet of GALEN in 24 healthy adult subjects under fasting condition

Settings and conduct

1- 24 healthy subjects enroll in this project. Volunteers provide written informed consent. They find to be healthy based on the history and physical examinations as well as clinical laboratory profiles. 2- A single dose of 4mg dexamethasone will administer, in each study period. 3-The Blood samples collect by direct vein punctures before and at 20, 40 min., 1, 1.5, 2, 2.5, 3, 3.5, 4, 6, 8 & 10 hours' post-dose. 4- The treatment phases separate by a washout period of at least 7 days. 5- Plasma samples will transfer to analytical Lab. to measuring dexamethasone in the plasma.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: - Aged between 20 - 50 years; Body weight between 50 – 100 kg; Having good health on the basis of medical history and physical & clinical examination. Exclusion criteria: Deviation from normal condition; donated a unit of blood or participated in another clinical trial, within the last two months; history of drug or alcohol abuse; smoke more than 10 cigarettes per day; use any prescription medication within 14 days, or any non-prescription medication within 7 days

Intervention groups

-Single dose of Dexamethasone 4mg tablet of Abureihan Pharm Co., -Single dose of Dexamethasone 4mg tablet of GALEN

Main outcome variables

Plasma concentration of Dexamethasone

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190706044111N10**
Registration date: **2019-09-15, 1398/06/24**
Registration timing: **prospective**

Last update: **2019-09-15, 1398/06/24**
Update count: **0**

Registration date

2019-09-15, 1398/06/24

Registrant information

Name
Ladan Tayebi

Name of organization / entity
Pars Biopharmacy Research Co.

Country
Iran (Islamic Republic of)

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+98 21 8895 6061

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2019-11-22, 1398/09/01
Expected recruitment end date
2020-03-18, 1398/12/28
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
A randomized, open label, two treatments, two periods, two sequence, single dose, crossover, bioequivalence study of Dexamethasone 4mg tablet of Abureihan Pharm Co., IRAN in comparison of Dexamethasone 4mg tablet of GALEN in 24 healthy adult subjects under fasting condition

Public title
Bioequivalence study of Dexamethasone 4mg tablet of Abureihan Pharm Co., IRAN
Purpose
Other
Inclusion/Exclusion criteria
Inclusion criteria:
Aged between 20 - 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 showed clinically relevant deviations from normal in physical examination. Subject had undergone surgery of the gastro-intestinal tract Subject had donated a unit of blood or participated in another clinical trial, within the last 8 weeks before the first treatment. 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: **24**
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 (Dexamethasone 4mg tablet of Abureihan Pharm Co.) and the other time reference product (Dexamethasone 4mg tablet of GALEN) with at least one week wash-out period.
Randomization (investigator's opinion)
Not randomized
Randomization description
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
2019-07-28, 1398/05/06
Ethics committee reference number
IR.ZAUMS.REC.1398.181

Health conditions studied

1

Description of health condition studied
Inflammatory diseases
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Plasma concentration of dexamethasone
Timepoint
Plasma related to 0, 20, 40 min., 1, 1.5, 2, 2.5, 3, 3.5, 4, 6, 8 and 10 hr. after dosing
Method of measurement
HPLC

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:Single dose of Dexamethasone 4mg tablet of Abureyhan Pharm Co.,
Category
Other

2

Description
Control group: Single dose of Dexamethasone 4mg tablet of GALEN
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Core Research Lab. of Zahedan University of Medical Sciences
Full name of responsible person
Gholamreza Komeili
Street address
Emam Ali Hospital, Salamat Blv., Khalij-e-Fars Highway
City
Zahedan
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Sistan-va-Balouchestan
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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
Aburaihan Pharm Co.
Full name of responsible person
Seifi Payam
Street address
No.1, Tirandaz Ave., Tehran-Pars
City
Tehran
Province
Tehran
Postal code
1654613111
Phone
+98 21 7770 7173
Fax
+98 21 7770 2066
Email
info@aburaihan.com
Web page address
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Aburaihan Pharm 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
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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Ladan Tayebi

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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