

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 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 AUC<sub>0-t</sub> and C<sub>max</sub>, 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)

##### Phone

+98 21 8895 6061

##### Email address

l.tayebi@parsbiopharmacy.com

#### 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

#### Province

Sistan-va-Balouchestan

#### Postal code

9816743111

#### Phone

+98 54 3329 5664

#### Fax

+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

#### Street address

1st floor, Saeidi Dd end, Felestin Ave.

#### City

Tehran

#### Province

Tehran

#### Postal code

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#### Phone

+98 21 8895 6061

#### Fax

+98 21 8896 9958

#### Email

l.tayebi@parsbiopharmacy.com

#### Web page address

## Person responsible for scientific 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**

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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

**Person responsible for updating data****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

**Street address**