Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Randomized, single-dose, crossover comparative bioequivalence study of Ondansetron 4 mg film-coated tablets of Aburaihan Pharmaceutical Co. and Zofran 4 mg film-coated tablet of Novartis Co. in 24 healthy male under fasting conditions

Protocol summary

Study aim
To demonstrate bioequivalence of single dose test formulation of Aburaihan Ondansetron 4 mg tablet with reference Zofran 4 mg tablet (Novartis Co.)

Design
Single dose, crossover bioequivalence study of Ondansetron 4 mg film-coated tablets (Aburaihan co.) with Zofran 4 mg film-coated tablets (Novartis co.) in 24 healthy male under fasting condition.

Settings and conduct
Study place: diabetes clinic affiliated to Shahid Beheshti endocrine research institute. Place for Blood and plasma sample analysis: TAVAN institute. Twenty four healthy male volunteers received each of two test or reference Ondansetron tablets in random sequence according to the randomization schedule. Receiving drug periods were 7 day apart from each other and after the washout period, subjects received the other product. Blood samples were taken from all participants before receiving the drug and 24 hours after that at determined time points for pharmacokinetic evaluations.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Healthy male subjects in the age range of 18-45 years and BMI (Body Mass Index) of 18.5-30. Exclusion criteria: subjects with a history of disease; BP (blood pressure) ≤ 90/60 mm/Hg or ≥ 140/90 mm/Hg.unusual measures in blood and clinical examination and heavy smokers.

Intervention groups
Intervention group 1 (Test): Ondansetron 4 mg film-coated Tablet, produced by Aburaihan pharmaceutical co. is the test product. In each period, 12 of 24 subjects will be given single oral dose of this product. Control group 2 (Reference): Zofran 4 mg film-coated Tablet (produced by Novartis co.) is the reference product. In each period, 12 of 24 subjects will be given single oral dose of this product.

Main outcome variables
Peak Plasma Concentration (Cmax); Area under the concentration-time curve (AUC)

General information

Reason for update

Acronym
Ondansetron

IRCT registration information
IRCT registration number: **IRCT20180620040164N2**
Registration date: **2019-05-12, 1398/02/22**
Registration timing: **retrospective**

Last update: **2019-05-12, 1398/02/22**
Update count: **0**

Registration date
2019-05-12, 1398/02/22

Registrant information

Name
Behzad Montaha Sangari

Name of organization / entity
Noor research and educational institute (Tavan)

Country
Iran (Islamic Republic of)

Phone
+98 21 6600 7026

Email address
info@tavaninstitute.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date

2018-12-22, 1397/10/01

Expected recruitment end date

2019-01-10, 1397/10/20

Actual recruitment start date

2018-12-22, 1397/10/01

Actual recruitment end date

2019-01-10, 1397/10/20

Trial completion date

2019-04-23, 1398/02/03

Scientific title

Randomized, single-dose, crossover comparative bioequivalence study of Ondansetron 4 mg film-coated tablets of Aburaihan Pharmaceutical Co. and Zofran 4 mg film-coated tablet of Novartis Co. in 24 healthy male under fasting conditions

Public title

Bioequivalence study of Ondansetron 4 mg film-coated tablet in 24 healthy male under fasting conditions

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Healthy subjects with BMI 18.5-30 kg/m2 Not having a history of any significant disease. Not having any abnormal finding in laboratory examination or during physical examination. Subjects who agree with patient consent form.

Exclusion criteria:

Known hypersensitivity or idiosyncratic reaction to Ondansetron or any ingredients. Subjects with BP ≤ 9060 mm/Hg or BP ≥ 140/90 mm/Hg Any evidence of impairment of renal, hepatic, cardiac, lung or gastrointestinal function or a history of TB, epilepsy, asthma (during past 5 years), DM, psychosis or glaucoma. Regular smoker who smokes more than ten cigarettes daily. Taking any medicine during two week before dosing

Age

From **18 years** old to **45 years** old

Gender

Male

Phase

Bioequivalence

Groups that have been masked

No information

Sample size

Target sample size: **24**

Actual sample size reached: **24**

Randomization (investigator's opinion)

Randomized

Randomization description

The sequence of taking test or reference product for each volunteer was determined according to the randomization schedule. The randomization schedule was prepared according to volunteer's allocated number. This number was allocated according to their entrance to volunteers' list in screening day

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

7th Floor, Builing No.2, Shahid Beheshti University of Medical Sciences, Arabi Ave, Daneshjoo Blvd, Velenjak

City

tehran

Province

Tehran

Postal code

19839-63113

Approval date

2018-12-03, 1397/09/12

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1397.167

Health conditions studied

1

Description of health condition studied

Bioequivalence investigation of the generic (Aburaihan co.) Ondansetron 4 mg tablet with brand (Novartis co.) zofran 4 mg 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 (Test): Ondansetron 4 mg film-coated tablet, produced by Aburaihan pharmaceutical co. 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 (Reference): Ondansetron 4 mg film-coated tablet, produced by Novartis pharmaceutical co. is the reference 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
Diabetes clinic, Shahid Beheshti research institute for endocrine sciences
Full name of responsible person
Dr. Amir Abbas Momenan
Street address
Yaman Ave., Velenjak
City
Tehran
Province
Tehran
Postal code
1985717413
Phone
+98 21 2243 2500
Email
info@endocrine.ac.ir
Web page address
http://endocrine.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Aburaihan pharmaceutical co.
Full name of responsible person
Payam Seifi
Street address
No. 1, infront of Hotel shahr, next to the Tehranpars cross
City
Tehran
Province
Tehran
Postal code
1654613111
Phone
+98 21 7770 7173
Fax
Email
info@aburaihan.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Aburaihan pharmaceutical co.
Proportion provided by this source
100
Public or private sector
Public
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
Tavan Institute
Full name of responsible person
Ali Aghaei
Position
Master
Latest degree
Master
Other areas of specialty/work
pharmacy
Street address
Unit 34, No. 69, Habibzadegan Ave., Teymuri St.,Tehran, Iran
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Email

info@tavaninstitute.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tavan Institute

Full name of responsible person

Seyed Mohsen Foroutan

Position

Principal investigator

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Ali Aghaei

Position

project manager

Latest degree

Master

Other areas of specialty/work

pharmacy

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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

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