Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Jul 2026

Randomized, single-dose, crossover comparative bioavailability study of the Marhamdarou zolpidem versus Stilnoct (Sanofi Company) in 24 healthy males under fasting conditions

Protocol summary

Study aim
To demonstrate bioequivalence of single dose test formulation of Marhamdarou zolpidem 10 mg tablet with reference stilnoct 10 mg tablet (Sanofi Co.) in healthy male subjects under fasting condition

Design
Bioequivalence crossover study to compare single-dose Zolpidem 10 mg tablets manufactured by Marhamdarou company and single-dose Stilnoct 10 mg tablets manufactured by Sanofi company 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 Zolpidem 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 12 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 18-55 years old; subjects with BMI (Body Mass Index) of 18.5-30. Exclusion criteria: subjects with medical history of disease; subjects with unusual measures in blood tests and clinical examination; subjects with physical or psychological dependence to narcotics.

Intervention groups
Intervention group 1 (Test): Zolpidem 10 mg Tablet, produced by Marham Darou is the test product. In each period, 12 of 24 subjects will be given single oral dose of this product. Control group (Reference): Stilnoct 10 mg Tablet (produced by Sanofi 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); Time of maximum measured plasma concentration (Tmax)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180620040164N1**
Registration date: **2018-12-06, 1397/09/15**
Registration timing: **retrospective**

Last update: **2018-12-06, 1397/09/15**
Update count: **0**

Registration date
2018-12-06, 1397/09/15

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

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-01-18, 1396/10/28

Expected recruitment end date
2018-01-25, 1396/11/05

Actual recruitment start date
2018-01-18, 1396/10/28
Actual recruitment end date
2018-01-25, 1396/11/05
Trial completion date
2018-08-01, 1397/05/10

Scientific title
Randomized, single-dose, crossover comparative bioavailability study of the Marhamdarou zolpidem versus Stilnoct (Sanofi Company) in 24 healthy males under fasting conditions

Public title
Bioequivalence study of zolpidem 10 mg 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 or any abnormal finding in laboratory examination or during physical examination Not physical or psychological dependence to narcotics
Exclusion criteria:
Known hypersensitivity to zolpidem or any ingredients. Obstructive sleep apnea Ingestion of a medicine (even herbal medicines), drugs for abuse or cigarette at any time within 7 days before dosing in Period-I (before the beginning of the study) History of any problem in blood donation Consumption of alcohol, grapefruit juice or caffeinated drinks 24 hours prior to the drug administration. Myasthenia gravis Severe hepatic insufficiency Acute and/or severe respiratory depression Any diseases that interacting with ADME (Absorption, Distribution, Metabolism & Excretion) procedures Psychotic illnesses Blood loss (>200 ml) during recent 60 days
Age
From **18 years** old to **55 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
2017-11-05, 1396/08/14
Ethics committee reference number
IR.SBMU.REC.1396.227

Health conditions studied

1

Description of health condition studied
comparative bioequivalence study of zolpidem 10 mg tablets of Marhamdarou Co. and Sanofi Co.
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
Time of maximum measured plasma concentration

(Tmax)

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): Zolpidem 10 mg Tablet, produced by Marham Darou 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

Control group (Reference): Stilnoct 10 mg Tablet (produced by Sanofi 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

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Email

info@endocrine.ac.ir

Web page address

http://endocrine.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Marham daru

Full name of responsible person

Mohammad jafar Rahmani

Street address

Payvand Bldg,NO. 46 A, Nezami Ganjavi St., Vali e Asr Ave, Tehran - Iran

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Email

Info@marhamdaru.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Marham daru

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

Tavan Institute

Full name of responsible person

Ali Aghaei

Position

Project manager

Latest degree

Master

Other areas of specialty/work

pharmacy

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Person responsible for scientific inquiries

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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
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