

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 (C_{max}); Time of maximum measured plasma concentration (T_{max})

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

Email address

info@tavaninstitute.ir

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

AgeFrom **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 (C_{max})**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
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Email
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Web page address
http://endocrine.ac.ir

Sponsors / Funding sources

- 1
Sponsor
Name of organization / entity
Marham daru

- Full name of responsible person**
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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
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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