Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Jul 2026

A study to compare the relative bioavailability of Aburaihan and MerckSerono 100 mcg tablet formulations of levothyroxine in 24 healthy adult volunteers under fasting conditions

Protocol summary

Study aim

The study aims to compare the bioequivalence of levothyroxine 100 mcg tablets under fasting conditions

Design

This randomized, single-dose, two-way, crossover study is conducted to compare the pharmacokinetic of levothyroxine and Euthyrox® tablets in 24 healthy adults male volunteers. Volunteers will be sorted and receive a number from 1 to 24. In the first phase of the study, 12 volunteers will receive levothyroxine manufactured by Aburaihan Pharmaceuticals and the remaining 12 volunteers will receive Euthyrox® produced by MerckSerono company. The administered drugs will be replaced by each other in the second phase of the study. Since in this study, the volunteers will receive both Test and Reference drugs, each volunteer will act as his own control.

Settings and conduct

The dose administration and subsequent sample collection will be performed in S. Motahhari hospital (Gonbade Kavous, Iran).

Participants/Inclusion and exclusion criteria

Males, 18-50 years of age. The subject is available for the entire study period and is willing to adhere to protocol requirements as evidenced by written informed consent. Good health at screening. Exclusion criteria: History of any drug hypersensitivity or intolerance. Significant history or current evidence of chronic disease. Receipt of any drug as part of a research study within 30 days prior to the present study.

Intervention groups

A single oral dose of 6 tablets of 100 mcg levothyroxine (600 mcg) manufactured by Aburaihan and MerckSerono companies

Main outcome variables

Drug plasma concentration; Area under the plasma concentration-time curve

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130626013776N13**
Registration date: **2019-08-19, 1398/05/28**
Registration timing: **prospective**

Last update: **2019-08-19, 1398/05/28**
Update count: **0**

Registration date

2019-08-19, 1398/05/28

Registrant information

Name

Hossein Amini

Name of organization / entity

Golestan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 17 1442 1651

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-23, 1398/06/01

Expected recruitment end date

2019-10-23, 1398/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
A study to compare the relative bioavailability of Aburaihan and MerckSerono 100 mcg tablet formulations of levothyroxine in 24 healthy adult volunteers under fasting conditions

Public title
Bioequivalence study of levothyroxine 100 mcg tablets under fasting conditions

Purpose
Health service research

Inclusion/Exclusion criteria

Inclusion criteria:
Males, 18-50 years of age. The subject is able and willing to provide signed informed consent. The subject is available for the entire study period and is willing to adhere to protocol requirements as evidenced by written informed consent. The subject has stable residence and telephone. Good health as determined by lack of clinically significant abnormalities in health assessments performed at screening.

Exclusion criteria:
History of allergy or sensitivity to levothyroxine. History of any drug hypersensitivity or intolerance which, in the opinion of the investigator,would compromise the safety of the subject of the study. Significant history or current evidence of chronic infectious disease, system disorder or organ dysfunction. Presence of gastrointestinal disease or history of malabsorption within the last year. History of a medical disorders occurring within the last year that required hospitalization or medication. Use of pharmacologic agents known to significantly induce or inhibit drug-metabolizing enzymes within 30 days prior to dosing. Receipt of any drug as part of a research study within 30 days prior to the present study. Donation or significant loss of whole blood (480 ml or more) within 30 days prior to the present study.

Age
From **18 years** old to **50 years** old

Gender
Male

Phase
Bioequivalence

Groups that have been masked
No information

Sample size
Target sample size: **24**

Randomization (investigator's opinion)
Randomized

Randomization description
According to the crossover design of the study, the twenty four participants randomized into two sequences of Test/Reference and Reference/Test products using command of rand in the Excel program.

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 Golestan University of Medical Sciences

Street address
Falsafi Building, Sari Road Km 5, Gorgan

City
Gorgan

Province
Golestan

Postal code
4916817693

Approval date
2019-07-21, 1398/04/30

Ethics committee reference number
IR.GOUMS.REC.1398.128

Health conditions studied

1

Description of health condition studied
.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Drug plasma concentration (T3 and T4)

Timepoint
0.5 and 0.25 and <5 min before drug administration and then 0.5, 1, 1.5, 2, 2.5, 3, 4, 6, 8, 10, 12, 24 and 48 hours after drug administration.

Method of measurement
Blood sampling and measurement of drug concentrations by ELISA (T3 and T4)

2

Description
Area under plasma concentration-time curve

Timepoint
0.5 and 0.25 and <5 min before drug administration and then 0.5, 1, 1.5, 2, 2.5, 3, 4, 6, 8, 10, 12, 24 and 48 hours after drug administration.

Method of measurement
Blood sampling and measurement of drug concentrations by ELISA (T3 and T4)

Secondary outcomes

1

Description
Time to reach Cmax
Timepoint
During 24 hours after drug administration
Method of measurement
Blood sampling and drug analysis by ELISA

Intervention groups

1

Description
Intervention group: Oral administration of a single 600 mcg dose of levothyroxine tablet manufactured by Aburaihan Pharmaceuticals to healthy volunteers
Category
Treatment - Drugs

2

Description
Intervention group: Oral administration of a single 600 mcg dose of Euthyrox tablet manufactured by MerckSerono to healthy volunteers
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Dialysis Center, S. Motahhari Hospital
Full name of responsible person
Yahya Naserifard
Street address
Taleghani Street
City
Gorgan
Province
Golestan
Postal code
4916817693
Phone
+98 17 3252 5972
Fax
+98 17 3252 5972
Email
haminhplc@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Aburaihan Pharmaceuticals
Full name of responsible person
Dr. Mosavi
Street address
Tirandaz Ave. No.1
City
Tehran
Province
Tehran
Postal code
1568-16765
Phone
+98 21 7770 7173
Fax
+98 21 7770 7176
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 Pharmaceuticals
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
Gorgan University of Medical Sciences
Full name of responsible person
Hossein Amini
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Data are confidential and need permission from the company.
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
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