

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 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

hamini@sbmu.ac.ir

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	Crossover
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	Other design features
Public title Bioequivalence study of levothyroxine 100 mcg tablets under fasting conditions	Secondary Ids empty
Purpose Health service research	Ethics committees
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.	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
Age From 18 years old to 50 years old	Health conditions studied
Gender Male	1 Description of health condition studied .
Phase Bioequivalence	ICD-10 code ICD-10 code description
Groups that have been masked No information	Primary outcomes
Sample size Target sample size: 24	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)
Randomization (investigator's opinion) Randomized	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)
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	

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 scientific inquiries

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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