

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Single-dose bioequivalence studies of Valsartan tablets (160 mg) in healthy volunteers

Protocol summary

Study aim

Administration of generic and reference products to healthy subjects Comparison of bioavailability and pharmacokinetics of two products Evaluation of interchangeability of two products

Design

26 healthy volunteers are divided into experimental and reference groups. For this purpose, first a total sample size of the candidates who met the inclusion criteria was determined and then 13 persons randomly assigned to the first group who use the test drug using the rand function of Excel software. And we assign another 13 people to the second group who receive the reference medicine. Then, in the second period, the group that received the test drug will receive the reference drug and the other group will receive the test drug. This clinical trial study with control group, double-blind, randomized, bioequivalence phase is performed on 26 patients.

Settings and conduct

This study was single-dose, randomized, and crossover. After completing the consent form and being aware of the drug and its side effects, the candidates consume the test product in one period and the reference product in the other period.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Healthy volunteers aged 18 to 50 years
Exclusion criteria: Age under 18 and over 50 and having any type of liver and kidney disease, etc.

Intervention groups

Experimental Group: Receiving a single dose of 160 mg oral Valsartan products from Hakim company to determine bio-equivalence Control Group: Receiving a single dose of 160 mg oral Valsartan reference product to determine bio-equivalence

Main outcome variables

The variables of this study include the maximum plasma concentration of the drug, the time to reach the maximum plasma concentration of the drug and the area

below the concentration versus time curve. The first two variables are a measure of drug uptake rate and the third variable is a measure of drug uptake.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170717035129N1**

Registration date: **2021-02-11, 1399/11/23**

Registration timing: **prospective**

Last update: **2021-02-11, 1399/11/23**

Update count: **0**

Registration date

2021-02-11, 1399/11/23

Registrant information

Name

Simin Dadashzadeh

Name of organization / entity

shahid Beheshti University of Medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 88200070

Email address

sdadashzadeh@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-12, 1399/11/24

Expected recruitment end date

2021-03-10, 1399/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Single-dose bioequivalence studies of Valsartan tablets (160 mg) in healthy volunteers

Public title

Bioequivalence of Valsartan tablets

Purpose

Other

Inclusion/Exclusion criteria**Inclusion criteria:**

Healthy volunteer Age: 18-50 year

Exclusion criteria:

History of liver, kidney and cardiovascular diseases that can affect drug clearance from body History of taking any medication in the last two weeks Creatinine above 2

Age

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

Gender

Both

Phase

Bioequivalence

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **26**

Randomization (investigator's opinion)

Randomized

Randomization description

In order to randomize, in this study, random allocation rule has been used. For this purpose, first a total sample size of the candidates who met the inclusion criteria was determined and then randomly assigned a number of 13 of them to the first group who use the test drug using the table of numbers. We assign the other 13 persons to the second group who receive the reference medicine. Then, in the second period, the group that received the test drug will receive the reference drug and the other group will receive the test drug

Blinding (investigator's opinion)

Double blinded

Blinding description

Candidates receive medication twice. Once Iranian product (generic) and once the foreign product (reference). The volunteers and the study physician do not know what product they received each time. Because the medicine is taken out of its box and blister and given to the volunteers, they will have no information about the type of medicine.

Placebo

Not used

Assignment

Crossover

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethical committee of School of Pharmacy Nursing and Midwifery, Shahid Beheshti Medical University

Street address

No 2660, School of Pharmacy Nursing and Midwifery, Shahid Beheshti Medical University, Niayesh building, Valiasr Ave

City

Tehran

Province

Tehran

Postal code

1996835113

Approval date

2020-08-23, 1399/06/02

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1399.183

Health conditions studied**1****Description of health condition studied**

Healthy subjects

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Plasma drug concentration

Timepoint

0.33, 0.66, 1, 2, 3, 4, 6, 8, 10, 12, 14, 24 Hours

Method of measurement

High performance liquid chromatography (HPLC) method

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Receiving Iranian medicine (generic product): In this group, each volunteer receives a 160 mg Valsartan tablets made by Hakim Company during a treatment period. After that, blood samples are taken from the volunteers for 24 hours. Blood samples (5 cc) are taken from volunteers at different times (14 times).

This completes a course of study. Pharmacokinetic parameters are calculated and compared by determining the drug concentration in blood samples by HPLC.

Category

Treatment - Drugs

2**Description**

Control group: Receiving reference medicine: In this group, each volunteer receives one reference tablet of 160 mg valsartan in a course of treatment. After that, blood samples are taken from the volunteers for 24 hours. Blood samples (5 cc) are taken from volunteers at different times (14 times). This completes a course of study. Pharmacokinetic parameters are calculated and compared by determining the drug concentration in blood samples by HPLC.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

School of Pharmacy, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Simin Dadashzadeh

Street address

No 2660, School of Pharmacy Nursing and Midwifery, Shahid Beheshti Medical University, Niayesh building, Valiasr Ave

City

Tehran

Province

Tehran

Postal code

1996835113

Phone

+98 21 8820 0115

Email

sdadashzadeh@sbmu.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Hakim Pharmaceutical Company

Full name of responsible person

Mehrdad Alimian

Street address

No. 1370 ,Dr. Shariati Ave. Gholhak, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

11155/4465

Phone

+98 21 2226 3051

Email

info@hakimpharm.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Hakim Pharmaceutical Company

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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Azadeh Haeri

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

No 2660, School of Pharmacy Nursing and Midwifery, Shahid Beheshti Medical University, Niayesh building, Valiasr Ave

City

Tehran

Province

Tehran

Postal code

1996835113

Phone

+98 21 8820 0212

Email

a_haeri@sbmu.ac.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Simin Dadashzadeh

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

No 2660, School of Pharmacy Nursing and Midwifery,
Shahid Beheshti Medical University, Niayesh building,
Valiasr Ave

City

Tehran

Province

Tehran

Postal code

1996835113

Phone

+98 21 8820 0115

Email

sdadashzadeh@sbmu.ac.ir

Valiasr Ave

City

Tehran

Province

Tehran

Postal code

1996835113

Phone

+98 21 8820 0115

Email

sdadashzadeh@sbmu.ac.ir

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

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

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Person responsible for updating data**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Simin Dadashzadeh

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

No 2660, School of Pharmacy Nursing and Midwifery,
Shahid Beheshti Medical University, Niayesh building,