# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

21 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
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**Phone**
+98 21 8820 0115
**Email**
sdadashzadeh@sbmu.ac.ir

## 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, Valiasr Ave
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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**
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