# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

09 Nov 2026

## In-vivo Bioequivalence Study of Silodosin 8 mg capsule of The Test Drug manufactured by Actoverco pharmacutical company in Compared with The Reference Drug Rapaflo 8 mg capsule

## Protocol summary

**Study aim**

In-vivo Bioequivalence Study of Silodosin 8 mg capsule of The Test Drug manufactured by Actoverco pharmacutical company

**Design**

Bioequivalence study, Cross-over design, Single dose, Single-blinded, 24 healthy volunteers, Two period, two week wash out period, Simple randomization method will be used.

**Settings and conduct**

This single-blind, two-period crossover study was conducted on two groups of healthy volunteers at Radin Shimi Company in Tabriz. Each period lasted 72hours, with a two -week washout interval between them. In the first period, based on computer-generated randomization, Group 1 received the reference drug while Group 2 received the test drug. In the second period, the treatments were switched. The study was single-blinded, meaning that participants were unaware whether they received the test or reference drug during either sampling period.

**Participants/Inclusion and exclusion criteria**

No history of heart, kidney & liver disease. The ages and BMIs of participant should be in the range of 18-55 and 18-30 respectively. Exclusion criteria: Smoking, Alcohol and drug addiction, History of allergy to drug, Pregnancy.

**Intervention groups**

Intervention group one receives Silodosin 8 mg capsule of The Test Drug manufactured by Actoverco pharmacutical company in the first round, and in the second round, after two-week washout period, the drug Rapaflo 8 mg . Intervention group No.2 receives the drugs in the switched order.

**Main outcome variables**

The concentration of the drug in blood, Time to reach maximum blood concentration, Extent of absorption

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20240804062647N28**
Registration date: **2026-05-16, 1405/02/26**
Registration timing: **prospective**

Last update: **2026-05-16, 1405/02/26**
Update count: **0**

**Registration date**

2026-05-16, 1405/02/26

**Registrant information**

**Name**

Massoud Amanlou

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

**Phone**

+98 21 6695 9067

**Email address**

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**Recruitment status**

**recruiting**

**Funding source**

**Expected recruitment start date**

2026-06-05, 1405/03/15

**Expected recruitment end date**

2027-06-05, 1406/03/15

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**
In-vivo Bioequivalence Study of Silodosin 8 mg capsule of The Test Drug manufactured by Actoverco pharmacutical company in Compared with The Reference Drug Rapaflo 8 mg capsule

**Public title**
In-vivo Bioequivalence Study of Silodosin 8 mg capsule of The Test Drug manufactured by Actoverco pharmacutical company

**Purpose**
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
General health (liver, heart, kidney) of volunteers Informed consent form Body mass index range (18-30) Age between18-55

**Exclusion criteria:**
Smoking Having a history of cardiovascular disease Having a history of liver & kidney disease Having a Alcohol & Drug addiction Having a hypersensitivity to the drug Pregnancy

**Age**
From **18 years** old to **55 years** old

**Gender**
Both

**Phase**
Bioequivalence

**Groups that have been masked**

- Participant

**Sample size**
Target sample size: **24**
More than 1 sample in each individual
Number of samples in each individual: **34**
Blood sample

**Randomization (investigator's opinion)**
Randomized

**Randomization description**
At first, all of the volunteers are evaluated for meeting inclusion criteria, selecting the final participants. Each volunteer is randomly assigned to a number between 1 and 24 using simple randomization, receiving an identification card containing the assigned number. Next, at first study period, volunteers with even numbers will receive the reference drug and volunteers with odd numbers will receive the test drug. In the second period, the formulations are switched in a cross-over design. The formulation assignment to the subjects is done randomly, with the participants and the trial staff not aware the formulation administered, thus, providing the blinding situation for all stages of the study.

**Blinding (investigator's opinion)**
Single blinded

**Blinding description**
This study is a single-blind (participant) clinical trial Silodosin 8 mg capsule of The Test Drug manufactured by Actoverco pharmacutical company and the original brand are removed from their packaging by the operator and placed in identical, coded cans. Volunteers are unaware of the type of drug or test they are receiving.

**Placebo**
Not used

**Assignment**
Crossover

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Tabriz University of Medical Sciences ethics committe

**Street address**
International Relations Office, No 2 Central Building, Tabriz University of Medical Sciences, Golgasht Street,

**City**
Tabriz

**Province**
East Azarbaijan

**Postal code**
5174864471

**Approval date**
2026-04-27, 1405/02/07

**Ethics committee reference number**
IR.TBZMED.REC.1405.081

## Health conditions studied

### 1

**Description of health condition studied**
This study is performed on healthy volunteers.

**ICD-10 code**

**ICD-10 code description**

## Primary outcomes

### 1

**Description**
The concentration of the drug in blood

**Timepoint**
0, 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 5, 6, 8, 10, 12, 24, 48, 72 h after drug

**Method of measurement**
Liquid Chromatography with Mass-Mass Detector

## Secondary outcomes

### 1

**Description**
Time to reach maximum blood concentration

**Timepoint**
After intervention

**Method of measurement**

The time to reach the maximum drug concentration in blood is recorded. This is done after completing the device analysis of the samples and through the WinNonLine software developed by Phoenix Company.

**2**

**Description**
Extent of absorption
**Timepoint**
After intervention
**Method of measurement**
Calculation of area under curve of concentration -time

## Intervention groups

**1**

**Description**
Intervention group: single dose of Silodosin 8 mg capsule of The Test Drug manufactured by Actoverco pharmacutical company , in the first period. Cross-over design with two week wash out period.After two week in the second period, a single dose of Rapaflo 8 mg
**Category**
Treatment - Drugs

**2**

**Description**
Intervention group: Single-dose of Rapaflo 8 mg, in the first period. Cross-over design with two week wash out period.After two week in the second period, a single dose of Silodosin 8 mg capsule of The Test Drug manufactured by Actoverco pharmacutical company
**Category**
Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Radin laboratory
**Full name of responsible person**
Bahram Ataii
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No.22, first floor, Moalem st., Abureihan St
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## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Actoverco Pharmaceutical Company
**Full name of responsible person**
Reza Karimi Mostofi
**Street address**
No58,Eighth ST,Nasr Alley,Tehran
**City**
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**Province**
Tehran
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1998678111
**Phone**
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**Email**
INFO@ACTOVERCO.COM
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Actoverco Pharmaceutical Company
**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**
Other

## Person responsible for general inquiries

**Contact**
**Name of organization / entity**
Tehran University of Medical Sciences
**Full name of responsible person**
Massoud Amanlou
**Position**
Academic staff and full-time professor of the Faculty of Pharmacy
**Latest degree**
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**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**
These data are as secure between researchers and related industries.
**Study Protocol**
No - There is not 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