

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

25 Jun 2026

### **In- Vivo Bioequivalence study of Clopidogrel 75 mg Tablets (SANA MED Pharma, Iran) with brand drug (PLAVIX® 75 mg SANOFI, USA) in Iranian healthy volunteers.**

#### **Protocol summary**

##### **Study aim**

In- Vivo Bioequivalence study of Clopidogrel 75 mg Tablets (SANA MED Pharma, Iran) with brand drug (PLAVIX® 75 mg SANOFI, USA) in Iranian healthy volunteers.

##### **Design**

Single dose, randomized, two sequences, two period crossover with a washout period.

##### **Settings and conduct**

This study will be conducted in single-dose, cross-over, and fasting, and on two sets of healthy volunteers. The study will be conducted in two periods of 72 hours. The interval between these two periods, which is called the wash-out time, is determined by the half-life of the drug plasma, which according to scientific sources should be at least 5 to 7 half-life of the drug in the case of the drug under study. The plan will take a week to clean up the drug, given the biological half-life of the drugs in the drug form. In the first round, candidates are divided into two groups, and the first group receives a test tablet and the second group receives similar tablets. Blood samples will be taken by the volunteer by the technician immediately after taking the drug, and the preparation steps of the samples, including plasma separation and drug extraction, are performed to analyze the amount of drug on them.

##### **Participants/Inclusion and exclusion criteria**

24 participants will be selected from non-smoking, not pregnant people with no history of heart, kidney, and liver disease or dysfunctions with both sexes (male&female). The ages and BMIs of the participants should be in the range of 18-60 and 18-28 respectively

##### **Intervention groups**

Single dose Clopidogrel 75 mg Tablets Sanamed Pharmaceuticals Company with brand drugs (PLAVIX® 75 mg SANOFI, USA)

##### **Main outcome variables**

Determination of blood drug concentration

#### **General information**

##### **Reason for update**

##### **Acronym**

##### **IRCT registration information**

IRCT registration number: **IRCT20200105046010N35**

Registration date: **2021-07-29, 1400/05/07**

Registration timing: **prospective**

Last update: **2021-07-29, 1400/05/07**

Update count: **0**

##### **Registration date**

2021-07-29, 1400/05/07

##### **Registrant information**

##### **Name**

Javad Shokri

##### **Name of organization / entity**

##### **Country**

Iran (Islamic Republic of)

##### **Phone**

+98 41 3661 4125

##### **Email address**

shokri.j@gmail.com

##### **Recruitment status**

**Recruitment complete**

##### **Funding source**

##### **Expected recruitment start date**

2021-08-01, 1400/05/10

##### **Expected recruitment end date**

2022-01-30, 1400/11/10

##### **Actual recruitment start date**

empty

##### **Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

In- Vivo Bioequivalence study of Clopidogrel 75 mg Tablets (SANA MED Pharma, Iran) with brand drug (PLAVIX® 75 mg SANOFI, USA) in Iranian healthy volunteers.

**Public title**

In-vivo Bioequivalence study of Clopidogrel tablet with brand drugs (PLAVIX SANOFI, USA)

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

General health Body mass index(18-28) Informed consent Age(18-60)

**Exclusion criteria:**

Smoking A history of cardiovascular disease A history of liver & kidney disease Pregnancy Alcohol & Drug addiction Hypersensitivity to the drug

**Age**

From **18 years** old to **60 years** old

**Gender**

Both

**Phase**

Bioequivalence

**Groups that have been masked**

- Participant

**Sample size**

Target sample size: **24**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

For this purpose, first determine a total sample size (24 people), then write the names of the people on paper, and after folding in aluminum foil, pour it into a glass, and then randomly remove the papers and open the first 12 people in group A and The rest are selected as group B.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

Clopidogrel and Clopidogrel brand are removed from their packaging by the executor and placed in similar and coded cans. Volunteers will not be informed about receiving the brand or test medications

**Placebo**

Not used

**Assignment**

Crossover

**Other design features****Secondary Ids**

empty

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

Ethics Committee, Tabriz University of Medical Sciences

**Street address**

Third floor of TUMS (Tabriz University of Medical Sciences) central building, Dneshgah St. Tabriz, Iran

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166614766

**Approval date**

2021-05-17, 1400/02/27

**Ethics committee reference number**

IR.TBZMED.REC.1400.157

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

Bio equivalence test

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

Determination of blood drug concentration.

**Timepoint**

Sampling times in this study will be 0, 1, 2, 2:30, 3, 3:20, 3:40, 4, 4:20, 4: 40, 5, 6, 8, 10, 12, 24, 48, 72 hours After prescribing the tablet.

**Method of measurement**

High Performance Liquid Chromatography with tandem mass spectroscopy detector

**Secondary outcomes**

empty

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

Intervention group: will receive one test drug tablet (Clopidogrel 75 mg SANA MED Pharma Pharmaceuticals). Blood samples will be taken from the volunteers for 72 hours at the mentioned times after drug administration and the concentration of Clopidogrel in blood samples will be measured by liquid chromatography with mass spectroscopy detector.

**Category**

Treatment - Other

## 2

### Description

Control group: will receive one test drug table (PLAVIX® 75 mg SANOFI, USA Pharmaceuticals). Blood samples will be taken from the volunteers for 72 hours at the mentioned times after drug administration and the concentration of Clopidogrel in blood samples will be measured by liquid chromatography with mass spectroscopy detector.

### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Simin Baspar Teyf Gostar Company

##### Full name of responsible person

Javad Shokri

##### Street address

No.48, Ferdos Street

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5167874434

##### Phone

+98 41 3384 2724

##### Email

Shokri.j@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

SanaMed Co.

##### Full name of responsible person

Farshid Malek Marzban

##### Street address

No.1, Hekmat alley, Bozorgmehr St,Valiasr St

##### City

Tehran

##### Province

Tehran

##### Postal code

۱۴۱۶۸۴۴۹۸۳

##### Phone

+98 21 6640 2684

##### Email

info@sanamedpharma.com

##### Grant name

##### Grant code / Reference number

##### Is the source of funding the same sponsor organization/entity?

Yes

##### Title of funding source

SanaMed Co.

##### 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

Tabriz University of Medical Sciences

##### Full name of responsible person

Javad Shokri

##### Position

Professor

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Medical Pharmacy

##### Street address

Faculty of Pharmacy, University of Medical Sciences, Daneshgah Street,Tabriz East Azerbaijan

##### City

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##### Province

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##### Postal code

5166414766

##### Phone

+98 41 3334 8489

##### Email

Shokri.j@gmail.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Full name of responsible person

Javad Shokri

##### Position

Professor

##### Latest degree

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##### Other areas of specialty/work

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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 researcher 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**

Yes - There is a plan to make this available

**Title and more details about the data/document**

Only protocol and methods of study are sharable

**When the data will become available and for how long**

Only protocol and methods of study are shareable.

**To whom data/document is available**

Pharmaceutical and medical sciences researchers

**Under which criteria data/document could be used**

Projects information's for any publications is not allowed.

**From where data/document is obtainable**

By email to the project manager (shokri.j@gmail.com)

**What processes are involved for a request to access data/document**

This information is confidential and is at the disposal of the project sponsor. Upon request, the information will be provided to the applicant by the contractor's email after the

**Comments**