

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### **In- Vivo Bioequivalence study of Esmoprazole 10 mg Sachet. Teb Mofid Nikan Co.(Pylorinex) with brand drugs (Nexium ® 10 mg Sachet, AstraZeneca, UK) in Iranian healthyvolunteers.**

#### **Protocol summary**

##### **Study aim**

In- Vivo Bioequivalence study of Esmoprazole 10 mg Sachet. Teb Mofid Nikan Co.(Pylorinex) with brand drugs (Nexium ® 10 mg Sachet, AstraZeneca, UK) in Iranian healthyvolunteers.

##### **Design**

In-vivo bioequivalence study of Esmoprazole 10 mg Sachet Mofid Pharma in comparison with reference drug (Nexium ® 10 mg Sachet, AstraZeneca, UK). The single blind, Cross-over, two period, two groups (Intervention and control) and randomized (paper lottery randomization method) study with one week wash-out time.

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

This study is carried out in Simin Baspar Tayf-Gostar Company, Tabriz, Iran. The study population is 24 healthy Iranian volunteers. This study is a single blind study and by taking out the drugs from the existing packaging, the volunteers will not know the time of receiving the test drug and the brand. This study is a cross over study that is performed in two time periods of 72 hours with a two-week wash-out period.

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

Inclusion criteria: age between 18-60 years old; body mass index (BMI) in the range of 18-28. Exclusion criteria: history of heart, kidney and liver disease; pregnancy; drug addiction.

##### **Intervention groups**

Single dose Esmoprazole 10 mg Sachet Mofid Pharma.  
Control group: Single dose Nexium ® 10 mg Sachet, AstraZeneca, UK

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

Plasma drug concentration

#### **General information**

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

##### **Acronym**

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

IRCT registration number: **IRCT20200105046010N71**  
Registration date: **2022-11-21, 1401/08/30**  
Registration timing: **registered\_while\_recruiting**

Last update: **2022-11-21, 1401/08/30**

Update count: **0**

##### **Registration date**

2022-11-21, 1401/08/30

##### **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**

2022-11-21, 1401/08/30

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

2023-06-20, 1402/03/30

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

empty

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

empty

##### **Trial completion date**

empty

##### **Scientific title**

In- Vivo Bioequivalence study of Esmoprazole 10 mg

Sachet. Teb Mofid Nikan Co.(Pylorinex) with brand drugs (Nexium ® 10 mg Sachet, AstraZeneca, UK) in Iranian healthyvolunteers.

#### Public title

In-vivo Bioequivalence Test of Ibuprofen tablet 800 mg Mofid Pharma with brand drug (Nexium ® 10 mg Sachet, AstraZeneca, UK)

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

General health Body mass index between18-28 Informed consent Being at the age of 18-55 years old

##### 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 **55 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, A 24- persons group will be selected and divided to two 12-persons groups randomly. The names of all volunteers will be written on paper pieces and wrapped in aluminum foils. The first 12 papers will randomly be withdrawn from bottle will be selected as group A and others will be categorized in group B.

#### Blinding (investigator's opinion)

Single blinded

#### Blinding description

Candidates are not aware of receiving the test drug or brand one. In a single study, information that could distort the test result is hidden from the candidates, but the person in charge of the test is aware of it. Test and Brand drugs 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 drug.

#### Placebo

Not used

#### Assignment

Crossover

#### Other design features

#### Secondary Ids

empty

#### Ethics committees

#### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Tabriz University of Medical Sciences

##### Street address

Third floor; Central building; Tabriz University of Medical Sciences; Dneshgah St.

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5166614766

#### Approval date

2022-10-24, 1401/08/02

#### Ethics committee reference number

IR.TBZMED.REC.1401.682

#### Health conditions studied

#### 1

#### Description of health condition studied

Plasma drug concentration

#### ICD-10 code

#### ICD-10 code description

#### Primary outcomes

#### 1

#### Description

Plasma drug concentration

#### Timepoint

Sampling times in this study will be 0, 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 4.5, 5, 6, 10 .8, 12 , 24 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: One test Sachet (Esmoprazole 10 mg Sachet. Teb Mofid Nikan Co.) will be received. Blood samples will be taken for 48 hours at the mentioned times after drug administration and the concentration of the drug in Plasma samples will be measured by liquid chromatography with mass spectroscopy detector

#### Category

Treatment - Other

## 2

### Description

Control group: One Reference tablet Nexium ® 10 mg Sachet, AstraZeneca, UK will be received. Blood samples will be taken for 24 hours at the mentioned times after drug administration and the concentration of drug in plasma 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. 10, 18-meter Mihrab St., Mirdamad St

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166934184

**Phone**

+98 41 3384 3199

**Email**

Shokri.j@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Teb Mofid Nikan Pharmaceutical Co.

**Full name of responsible person**

Mohammad Reza Zargarzadeh

**Street address**

No. 275, Shafayab Building, 6th Floor, Beheshti St.,  
Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

3361658369

**Phone**

+98 21 8817 5765

**Email**

info@mofidpharma.com

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

Yes

**Title of funding source**

Teb Mofid Nikan Pharmaceutical 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**

Persons

## Person responsible for general inquiries

#### Contact

**Name of organization / entity**

Simin Baspar Teyf Gostar Company

**Full name of responsible person**

Dariush Omidfar

**Position**

Lab. Manager

**Latest degree**

Master

**Other areas of specialty/work**

Bioanalysis

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## 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**

Ph.D.

**Other areas of specialty/work**

Medical Pharmacy

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Sciences, Daneshgah

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

Simin Baspar Teyf Gostar Company

**Full name of responsible person**

Ahad Sheikhloo

**Position**

Official Manager

**Latest degree**

Master

**Other areas of specialty/work**

Biochemistry

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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**

All information and data of the study will remain secured based on the agreement established between researcher and drug producer.

**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**

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