# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

18 Sep 2026

## A study to compare the relative bioavailability of Sanamed and Novartis tablet formulations of Sodium Diclofenac 100 mg in 24 healthy adult volunteers under fasting conditions

## Protocol summary

**Study aim**

Bioequivalence evaluation of two formulations of sodium diclofenac tablets in healthy subjects under fasting conditions

**Design**

This randomized, single-dose, not blinded, two-way, crossover study is conducted to compare the pharmacokinetics of sodium diclofenac and Voltaren® tablets in 24 healthy adult volunteers. Volunteers will receive a number from 1 to 24 according to the pot randomization method. In the first period of the study, 12 volunteers will receive sodium diclofenac-Sanamed tablet and the remaining 12 volunteers will receive Voltaren®-Novartis tablet. The administered drugs will be replaced to another group in the second period of the study.

**Settings and conduct**

The dose administration and subsequent sample collection will be performed in Motahhari hospital (Gonbade Kavous, Iran).

**Participants/Inclusion and exclusion criteria**

Inclusion criteria: aged 18-55 years old; subject available for the entire study period; willingness to adhere to protocol requirements as evidenced by written informed consent; good health at screening. Exclusion criteria: History of use of any drug; hypersensitivity or intolerance; significant history or current evidence of chronic disease; receipt of any drug as part of a research study within 30 days prior to the present study.

**Intervention groups**

First intervention group: A single 100 mg oral dose of sodium diclofenac tablet manufactured by Sanamed company to 12 subjects. Second intervention group: A single 100 mg oral dose of Voltaren tablet manufactured by Novartis company to 12 subjects. Volunteers will receive both test and reference products and each volunteer will therefore act as his own control.

**Main outcome variables**

Drug plasma concentration; Area under the plasma concentration-time curve

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20130626013776N104**
Registration date: **2022-11-22, 1401/09/01**
Registration timing: **prospective**

Last update: **2022-11-22, 1401/09/01**
Update count: **0**

**Registration date**

2022-11-22, 1401/09/01

**Registrant information**

**Name**
Hossein Amini
**Name of organization / entity**
Golestan University of Medical Sciences
**Country**
Iran (Islamic Republic of)
**Phone**
+98 17 1442 1651
**Email address**
hamini@sbmu.ac.ir

**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2022-12-22, 1401/10/01

**Expected recruitment end date**

2023-08-23, 1402/06/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

A study to compare the relative bioavailability of Sanamed and Novartis tablet formulations of Sodium Diclofenac 100 mg in 24 healthy adult volunteers under fasting conditions

**Public title**

Bioequivalence study of Sodium Diclofenac 100 mg tablets

**Purpose**

Basic scienece

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

18-55 years of age. The subject is able and willing to provide signed informed consent. The subject is available for the entire study period. Willing to adhere to protocol requirements as evidenced by written informed consent. The subject has a stable residence and telephone. Good health as determined by lack of clinically significant abnormalities in health assessments performed at screening.

**Exclusion criteria:**

History of allergy or sensitivity to Diclofenac. History of any drug hypersensitivity or intolerance which, in the opinion of the investigator,would compromise the safety of the subject of the study. Significant history or current evidence of chronic infectious disease, system disorder or organ dysfunction. Presence of gastrointestinal disease or history of malabsorption within the last year. History of a medical disorders occurring within the last year that required hospitalization or medication. Use of pharmacologic agents known to significantly induce or inhibit drug-metabolizing enzymes within 30 days prior to dosing. Receipt of any drug as part of a research study within 30 days prior to the present study. Donation or significant loss of whole blood (480 ml or more) within 30 days prior to the present study.

**Age**

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

**Gender**

Both

**Phase**

Bioequivalence

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **24**

More than 1 sample in each individual

Number of samples in each individual: **2**

In a crossover design, each person is its own control and receives two different interventions

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

A pot sampling method will be used in this study. 12 papers are labeled "Reference Product" and 12 papers are written as "Test Product". The papers are then placed in sealed envelopes, and participants randomly select a paper and will be placed in the Reference or Test groups.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description**

**Placebo**

Not used

**Assignment**

Crossover

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Ethics Committee of Golestan University of Medical Sciences

**Street address**

Falsafi Building, Sari Road Km 2

**City**

Gorgan

**Province**

Golestan

**Postal code**

4934174515

**Approval date**

2022-10-09, 1401/07/17

**Ethics committee reference number**

IR.GOUMS.REC.1401.345

## Health conditions studied

### 1

**Description of health condition studied**

.

**ICD-10 code**

**ICD-10 code description**

## Primary outcomes

### 1

**Description**

Maximum drug plasma concentration

**Timepoint**

At time zero and 1, 1.5, 2, 2.5, 3, 3.5, 4, 5, 6, 8, 10 and 12 h after drug administration

**Method of measurement**

Blood sampling and measurement of drug concentrations by high-performance liquid chromatography

### 2

**Description**

Area under the plasma drug concentration-time curve

**Timepoint**

At time zero and 1, 1.5, 2, 2.5, 3, 3.5, 4, 5, 6, 8, 10 and 12 h after drug administration

**Method of measurement**

Blood sampling and measurement of drug concentrations by high-performance liquid chromatography

## Secondary outcomes

### 1

**Description**

Plasma half-life

**Timepoint**

From the terminal 6 hours of plasma concentration-time profile

**Method of measurement**

Blood sampling and drug analysis by high-performance liquid chromatography method

## Intervention groups

### 1

**Description**

Intervention group 1: Oral administration of a single 100 mg dose of sodium diclofenac (1 tablet) manufactured by Sanamed to healthy volunteers under fasting conditions in the morning of the experiment day

**Category**

Treatment - Drugs

### 2

**Description**

Intervention group 2: Oral administration of a single 100 mg dose of Voltaren (1 tablet) manufactured by Novartis to healthy volunteers under fasting conditions in the morning of the experiment day

**Category**

Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**

Dialysis Center, S. Motahhari Hospital

**Full name of responsible person**

Yahya Naserifard

**Street address**

Taleghani Street

**City**

Gonbade Kavous

**Province**

Golestan

**Postal code**

4916817693

**Phone**

+98 17 3252 5972

**Fax**

+98 17 3252 5972

**Email**

haminhplc@yahoo.com

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Sanamed Pharmaceuticals

**Full name of responsible person**

Dr. Maryam Haji Akhondi

**Street address**

Km.19 Karaj Special Road, Across from Vardavard Town, Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

3593147655

**Phone**

+98 21 6640 2684

**Fax**

+98 21 6640 2684

**Email**

info@sanamedpharma.com

**Web page address**

http://sanamedpharma.com

**Grant name**

Bioequivalence Study of Diclofenac

**Grant code / Reference number**

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

Yes

**Title of funding source**

Sanamed Pharmaceuticals

**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**

Industry

## Person responsible for general inquiries

**Contact**

**Name of organization / entity**

Gorgan University of Medical Sciences

**Full name of responsible person**

Hossein Amini

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**
Medical Pharmacy
**Street address**
Sari Road, Km 2
**City**
Gorgan
**Province**
Golestan
**Postal code**
4934174515
**Phone**
+98 17 3252 5972
**Fax**
+98 17 3252 5972
**Email**
haminhplc@yahoo.com

## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Gorgan University of Medical Sciences
**Full name of responsible person**
Hossein Amini
**Position**
Associate professor
**Latest degree**
Ph.D.
**Other areas of specialty/work**
Medical Pharmacy
**Street address**
Sari Road, Km 2
**City**
Gorgan
**Province**
Golestan
**Postal code**
4934174515
**Phone**
+98 17 3252 5972
**Fax**
+98 17 3252 5972
**Email**
haminhplc@yahoo.com

## Person responsible for updating data

**Contact**
**Name of organization / entity**
Gorgan University of Medical Sciences
**Full name of responsible person**
Hossein Amini
**Position**
Associate professor
**Latest degree**
Ph.D.
**Other areas of specialty/work**
Medical Pharmacy
**Street address**
Sari Road, Km 2
**City**
Gorgan
**Province**
Golestan
**Postal code**
4934174515
**Phone**
+98 17 3252 5972
**Fax**
+98 17 3252 5972
**Email**
haminhplc@yahoo.com

## 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**
Data are confidential and need permission from the company.
**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