

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Comparative bioequivalence study of the Budesonide 9 mg, tablet manufactured by Tasnim Company

#### Protocol summary

##### Study aim

Examining the bioequivalency of the Budesonide 9-mg tablets manufactured by Tasnim Company with brand samples(Cortimen®)

##### Design

A single dose, not blinded, randomized, bioequivalence clinical trial on 24 healthy volunteers.

##### Settings and conduct

The number of 24 healthy in the age range of 18-60 years and the Body Mass Index range of 18-30, who are voluntarily selected through public notification. One tablet is taken fasting and blood is taken at 16 times point. One week later, the process is repeated for the brand medicine

##### Participants/Inclusion and exclusion criteria

The weight range of participating candidates should be between 60-100 kg; All candidates must be non-smokers; Candidates should be healthy in terms of physical examination, ECG and the following laboratory tests: Hemoglobin, Hematocrit, Red and White Blood Count, MCV (Mean Body Volume), MCH (Mean Body Hemoglobin), Routine Urinalysis, Total Cholesterol, Triglyceride, Total Proteins, albumin, uric acid, total bilirubin, alkaline phosphatase, gamma glutamyl transpeptidase ( $\gamma$ -GT), aspartate aminotransferase (AST), alanine aminotransferase (ALT), urea, creatinine and fasting blood glucose Volunteers who have agreed to an informed consent form.

##### Intervention groups

After taking a Budesonide 9-mg tablets from domestic company, 3 milliliters of blood will be collected from the volunteer in 16 times intervals for 72 hours. one week later, the process is repeated for a brand sample tablet. The drug concentration is measured in plasma

##### Main outcome variables

Studying the Drug pharmacokinetic parameters including measuring the plasma concentrations of drugs for brand and test products, determining the desired and important pharmacokinetic parameters in bioequivalence

studies, AUCs, Tmax, Cmax, T1/2

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20130313012810N23**

Registration date: **2024-01-21, 1402/11/01**

Registration timing: **retrospective**

Last update: **2024-01-21, 1402/11/01**

Update count: **0**

##### Registration date

2024-01-21, 1402/11/01

##### Registrant information

##### Name

Hamed Hamishehkar

##### Name of organization / entity

Drug Applied Research Center, Tabriz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 1336 3311

##### Email address

hamishehkar.hamed@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2024-01-15, 1402/10/25

##### Expected recruitment end date

2024-01-19, 1402/10/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
Comparative bioequivalence study of the Budesonide 9 mg, tablet manufactured by Tasnim Company

**Public title**  
Budesonide tablet bioequivalence

**Purpose**  
Other

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
The weight range of participating candidates should be between 60-100 kg Candidates should be healthy in terms of physical examination, ECG and the following laboratory tests: Hemoglobin, Hematocrit, Red and White Blood Count, MCV (Mean Body Volume), MCH (Mean Body Hemoglobin), Routine Urinalysis, Total Cholesterol, Triglyceride, Total Proteins, albumin, uric acid, total bilirubin, alkaline phosphatase, gamma glutamyl transpeptidase (γ-GT), aspartate aminotransferase (AST), alanine aminotransferase (ALT), urea, creatinine and fasting blood glucose Volunteers who have agreed to an informed consent form All candidates should not consume caffeine-containing drinks and chocolate during two days before the prescription, and this restriction must be followed until the last blood draw

**Exclusion criteria:**  
History of allergic or adverse reaction to Budesonide or any similar product Volunteers with blood pressure less than 60/90 mm Hg or higher than 90/140 mm Hg Smokers Individuals who donated whole blood or blood components within 2 months within 2 weeks prior to the first dose of the study product(s)

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

**Gender**  
Both

**Phase**  
Bioequivalence

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **24**

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

**Randomization description**  
To randomly assign people in two groups, 24 cards with numbers 1 to 24 will be used in closed envelopes that are arranged irregularly. Each candidate will pick up an envelope after entering the study, and numbers 1-12 will be in group A and numbers 13-24 will be in group B. Group A will receive intervention 1 and group B will receive intervention 2, and after the first period, the interventions of the both groups will change for the second period.

**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 Tabriz University of Medical Sciences

##### Street address

Daneshgah St. Drug Applied Research Center

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5165665811

#### Approval date

2023-12-18, 1402/09/27

#### Ethics committee reference number

IR.TBZMED.REC.1402.697

## Health conditions studied

### 1

#### Description of health condition studied

Bioequivalence study in healthy volunteers

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Plasma concentration of the drug

#### Timepoint

16 sampling time included pre-dose (time 0) and at the following hours post-dose: 1, 2, 3, 4, 6, 8, 10, 12, 13, 14, 24, 48, and 72 h

#### Method of measurement

Liquid Chromatography with tandem mass spectrometry (LC-MS-MS)

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: This study examines the bioequivalence of the Budesonide tablet produced by a domestic company with a foreign brand sample. We have only one intervention group and there is no control group. The intervention group, which includes healthy, fasting volunteers, will receive a single dose, 9 mg tablet manufactured by the pharmaceutical company Tasnim and Cortimen® brand, in two 72-hour periods with an interval of one week, on the day of the study. And in 16 different time periods up to 72 hours after taking the medicine, blood samples will be taken from the volunteers in the amount of 3 ml each time, that is, a total of 48 ml within 72 hours. The training that will be given to the volunteers includes avoiding the consumption of drinks containing alcohol and xanthine and other interfering drugs in the prescription drug from 48 hours before the start of the study until the end of the study.

**Category**

N/A

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Drug Applied Research Center, Tabriz University of Medical Sciences

**Full name of responsible person**

Hamed Hamishehkar

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Tasnim pharmaceutical Company

**Full name of responsible person**

Nazanin Nami Moghaddam

**Street address**

Tasnim Building, No. 3, 14th East Street, Beyhaghi Street, Argentina Square, Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1515667911

**Phone**

+98 21 8817 4810

**Email**

info@tasnimpharma.com

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

Yes

**Title of funding source**

Tasnim 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**

Industry

**Person responsible for general inquiries****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Hamed Hamishehkar

**Position**

Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Pharmacy

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**Contact**

**Name of organization / entity**

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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**

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