Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 (γ-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)

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+98 41 1336 3311

Email address

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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

Daneshghah 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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Person responsible for scientific inquiries

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Position
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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