

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

In- Vivo Bioequivalence study of (Acetaminophene/ Phenylephrine/ Chlorpheniramine/ Dextrometorphane) tablet 500/2/5/15mg Loghman (Cafocold) with brand drugs (Tylenol COLD + FLU SEVERE®) in Iranian healthy volunteers.

Protocol summary

Study aim

In-vivo Bioequivalence study of Acetaminophene/ Phenylephrine/ Chlorpheniramine/ Dextrometorphane) tablet 500/2/5/15mg Loghman (Cafocold) with brand drugs (Tylenol COLD + FLU SEVERE®) 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 two-way, cross-over and fasting, and on two sets of healthy volunteers. The study will be conducted in two time periods. 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 a similar tablet. Blood samples are taken by the volunteer by the doctor 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 disfunctions with both sex (male & female). The ages and BMIs of participant should be in the range of 18-60 and 18-25 respectively.

Intervention groups

Both groups received in cross-over design medication and testing at two different cross-sections and

Therefore, the test results are independent of individual differences and it will only show the difference in the formulation of the two drugs.

Main outcome variables

C_{max}, T_{max}, T_{1/2}, K_e (Elimination)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200105046010N3**

Registration date: **2020-06-12, 1399/03/23**

Registration timing: **registered_while_recruiting**

Last update: **2020-06-12, 1399/03/23**

Update count: **0**

Registration date

2020-06-12, 1399/03/23

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

2020-05-25, 1399/03/05

Expected recruitment end date

2020-12-05, 1399/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

In- Vivo Bioequivalence study of (Acetaminophene/ Phenylephrine/ Chlorpheniramine/ Dextrometorphane) tablet 500/2/5/15mg Loghman (Cafocold) with brand drugs (Tylenol COLD + FLU SEVERE®) in Iranian healthy volunteers.

Public title

Test7 Cold Pills tablet (Acetaminophen / Phenylephrine / Chlorpheniramine / Dextromethorphan 500/2/15 / 15mg)n-vivo Bioequivalence study in Iranian healthy volunteers.

Purpose

Other

Inclusion/Exclusion criteria**Inclusion criteria:**

General health(liver&heart&kidney) Body mass index(18-55) Informed consent Age(18-60)

Exclusion criteria:

Smoking History of cardiovascular disease 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

Individuals are randomly selected with advertising 24 volunteers categorized in two sequences randomly.the type of drug (Sample and Brand drug)will prescribe with lottery.

Blinding (investigator's opinion)

Single blinded

Blinding description

Candidates are not aware of the test drug or brand drug

Placebo

Not used

Assignment

Crossover

Other design features

Two periode/Two sequence with a washout time

Secondary Ids

empty

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

Tabriz University of Medical Sciences ethics committee

Street address

No.48,Ferdows street, Ferdowsi Sq.

City

Tabriz

Province

East Azarbaijan

Postal code

51678744

Approval date

2020-05-19, 1399/02/30

Ethics committee reference number

IR. TBZMED. REC.1398.1301

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

Healthy volunteers

ICD-10 code

empty

ICD-10 code description

empty

Primary outcomes**1****Description**

Plasma drug concentrations

Timepoint

hour

Method of measurement

HPLC,LC-MS/MS or UPLC-MS/MS

Secondary outcomes**1****Description**

Pharmacokinetic parameters

Timepoint

Immediately after the intervention

Method of measurement

Theoretically and using pharmacokinetic equations

Intervention groups

1

Description

In Crossover study with two intervention groups. Intervention group one (sequence1,volunteers No:1-12)

Category

Other

2

Description

Intervention group two (sequence2,volunteers No:13-24) without control group based on the guidelines of FDA for bioequivalence study. Intervention parameters including: type & dose of the drug, type of dosage form, sampling intervals, sample preparation method, feeding or fasting conditions, analytical method and individual differences between subject. single dose, randomized, double blind, two ways, two periods study.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Simin Baspar Teyf Gostar Company

Full name of responsible person

Javad Shokri

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No.48,Ferdos Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Hamid Mostafavi

Street address

Loghman darou Pharmaceutical Company

City

Tehran

Province

Tehran

Postal code

1389737611

Phone

+98 21 4450 4121

Email

info@loghmanpharma.com

Grant name

Grant code / Reference number

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

No

Title of funding source

Loghman Daruo 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

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

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Person responsible for scientific inquiries

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

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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

Yes - There is 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

After finishing of the protocol (Probably 6 months receiving IRCT code)

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

Contact with E-mail of the main researcher.

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

Personal and academic details and the aim of the request.

Comments