Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 Therefor,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

Cmax,Tmax, T1/2, Ke(Elemination)

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

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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) Informad 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 committe
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 pharmacakinetic 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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Hamid Mostafavi
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Loghman darou Pharmaceutical Company
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Tehran
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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
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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 date 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