Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jul 2026

Bioequivalence Evaluation of Losartan and Cozaar® formulations in healthy volunteers

Protocol summary

Study aim
bioequivalence evaluation of losartan and cozaar® formulations in healthy volunteers

Design
A randomized, two-treatment, two-period, cross over study

Settings and conduct
26 healthy subjects are enrolled. The study is single-blind. Following an overnight fast of at least 10 hours, the drug product is administered. In each treatment period, under supervision of study investigators, a single dose of 50 mg of Losartan is administered orally with 240 ml of water to subjects. No food is allowed for at least 4 hours post-dose. Water is allowed as desired except for one hour before and after drug administration. For the measurement of pharmacokinetic parameters, 5 ml blood samples are taken before (0 min) and at 0.33, 0.66, 1, 1.5, 2, 2.5, 3, 3.5, 4, 5, 6, 8, 10 and 24 hours after administration. The subjects spend approximately 11 hours at the study location during each treatment phase, starting 1 hour before dosing until 10 hours afterwards. The subjects show up for a post-study visit 24 after the dosing.

Participants/Inclusion and exclusion criteria
inclusion criteria: healthy volunteers exclusion criteria: Significant history or presence of gastrointestinal, kidney disease or any other conditions known to interfere with the absorption, distribution, metabolism or excretion of common medications. Any clinically significant illness during the 4 weeks prior to day of this study.

Intervention groups
The administration of two products is carried out by a randomized and crossover study design. Subjects are randomly divided into two equal groups and assigned to one of the two sequences of drug administration.

Main outcome variables
Bioequivalence, Losartan, Pharmacokinetics

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130603013572N5**
Registration date: **2020-09-07, 1399/06/17**
Registration timing: **registered_while_recruiting**

Last update: **2020-09-07, 1399/06/17**
Update count: **0**

Registration date
2020-09-07, 1399/06/17

Registrant information

Name
Mohammadreza Rouini

Name of organization / entity
Tehran University of Medical Sciences, Faculty of Pharmacy

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-02-20, 1398/12/01

Expected recruitment end date
2021-02-19, 1399/12/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Bioequivalence Evaluation of Losartan and Cozaar® formulations in healthy volunteers

Public title
Bioequivalence Evaluation of Losartan and Cozaar® formulations in healthy volunteers

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
in healthy male and female volunteers

Exclusion criteria:
History of hypersensitivity to the study drug or related products. Significant history or presence of gastrointestinal, kidney disease or any otherconditions known to interfere with the absorption, distribution, metabolism orexcretion of common medications. Significant history of asthma, chronic bronchitis or other bronchospasticcondition. Significant history or presence of glaucoma, cardiovascular or hematologicaldisease. Any clinically significant illness during the 4 weeks prior to day of this study. Maintenance therapy with any drug, or history of drug dependency, alcoholabuse, or serious neurological or psychological disease. Participation in a clinical trial with an investigation drug within 30 dayspreceding day 1 of this study. Use of enzyme-modifying drugs within 30 days prior to day 1 of this study. Use of any systemic medication (including OTC preparations) within 14 daysprior day 1 of this study. HIV and Hepatitis B and anti HCV antibody positive subjects. Smoking History of difficulty in donating blood Donation of blood within 90 days before first dosing. History of vaccination within one month before first dosing.

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

Gender
Both

Phase
Bioequivalence

Groups that have been masked

- Participant

Sample size
Target sample size: **26**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization administrating of test or reference product for each subject is determined according to the randomization schedule. The randomization schedule is prepared according to volunteer's allocated number. Each subject is identified by a number from 1 to 24 according to their entrance to volunteers' list in screening day. Randomly, Subjects with odd numbers receive the test drug and the subjects with even number receive the reference drug.

Blinding (investigator's opinion)
Single blinded

Blinding description
Volunteers are blind in this study. The volunteers, according to the predetermined random table that is available to the researcher, are in one of the groups receiving the test or reference drug. Volunteers are aware that they are receiving the test drug (Iranian) and the reference drug (approved drug), but they do not know in which study period they will receive the test and reference drug.

Placebo
Not used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Vice-chancellor in research affairs- Tehran university of medical sciences

Street address
Keshavarz Blvd., Tehran, Iran

City
tehran

Province
Tehran

Postal code
1416753955

Approval date
2020-02-04, 1398/11/15

Ethics committee reference number
IR.TUMS.VCR.REC.1398.879

Health conditions studied

1

Description of health condition studied
Pharmacokinetics, Losartan , Bioequivalent

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
determination of drug concentration in blood plasma

Timepoint
0 min and at 0.33, 0.66, 1, 1.5, 2, 2.5, 3, 3.5, 4, 5, 6, 8, 10 and 24 hours after drug administration.

Method of measurement
blood samples collection

Secondary outcomes

1

Description
time to peak plasma concentration
Timepoint
0 min and at 0.33, 0.66, 1, 1.5, 2, 2.5, 3, 3.5, 4, 5, 6, 8, 10 and 24 hours
Method of measurement
observational

2

Description
maximum plasma concentration
Timepoint
0 min and at 0.33, 0.66, 1, 1.5, 2, 2.5, 3, 3.5, 4, 5, 6, 8, 10 and 24 hours
Method of measurement
observational

3

Description
Area under the plasma concentration–time curves
Timepoint
0 min and at 0.33, 0.66, 1, 1.5, 2, 2.5, 3, 3.5, 4, 5, 6, 8, 10 and 24 hours
Method of measurement
linear trapezoidal method

Intervention groups

1

Description
Intervention group: 50 mg oral tablet of Losaratan (Dana pharmaceutical company), once daily
Category
Other

2

Description
Control group: 50 mg oral tablet of Cozaar (merck), once daily
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Tehran university of medical sciences
Full name of responsible person
Dr. Mohammadreza Rouini
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Sponsors / Funding sources

1

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Name of organization / entity
Daana pharma.Co
Full name of responsible person
mr. Ahmad Kharazi
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Email
office@daanapharma.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Daana pharma.Co
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
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Dr. Mohammadreza Rouini
Position
Professor
Latest degree

Ph.D.

Other areas of specialty/work
Pharmaceutics and Biopharmaceutics

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
Only protocol and methods of study are shareable

When the data will become available and for how long
Starting access 6 months after publication of data

To whom data/document is available
Pharmaceutical and medical sciences researchers

Under which criteria data/document could be used
Using is not authorized

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 data request.

Comments