Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Bio equivalence study of Hydrochlorothiazide 50 mg tablets manufactured by Fatak Chemie Pars pharmaceutical company and comparing pharmacokinetics results with Hydrochlorothiazide tablets manufactured by Novartis in healthy volunteers

Protocol summary

Study aim
Comparing pharmacokinetics parameters of Fatak Chemie Pars Hydrochlorothiazide 50 mg tablets and Hydrochlorothiazide tablet of Novartis company.

Design
Clinical trial of control and intervention groups, crossover, double-blind, randomized, on 24 volunteers. One number from 1 to 24 will be allocated to each healthy volunteers. Then Extraction of 12 numbers (from 1 to 24) is carried out using https://kitset.ir/numbers/random#random-number-form. These first 12 random numbers create the first group.

Settings and conduct
Bioequivalance Hydrochlorothiazide 50 mg study will be performed under physician since 7 AM until 7 PM.This study is carried out as a cross over double blind investigation. The blind person included volunteers, administrator and analyst.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Healthy liver and kidney; observing BMI limits. Non-inclusion criteria: smoking; pregnancy

Intervention groups
Intervention group: One Hydrochlorothiazide 50 mg tablet manufactured by Fatak Chime Pars Company (Test drug) is administrated to each of 12 healthy. Control group: 2 Hydrochlorothiazide 25 mg tablet manufactured by NOVARTIS Company is administrated.

Main outcome variables
Maximum concentration (Cmax), maximum time (Tmax), area under the curve (AUC)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200513047423N4**
Registration date: **2021-11-28, 1400/09/07**
Registration timing: **prospective**

Last update: **2021-11-28, 1400/09/07**
Update count: **0**

Registration date
2021-11-28, 1400/09/07

Registrant information

Name
Amir Mehdizadeh

Name of organization / entity
Ofogh pajo

Country
Iran (Islamic Republic of)

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ofoghfarmed.lab@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-12-03, 1400/09/12

Expected recruitment end date
2021-12-24, 1400/10/03

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Bio equivalence study of Hydrochlorothiazide 50 mg

tablets manufactured by Fatak Chemie Pars pharmaceutical company and comparing pharmacokinetics results with Hydrochlorothiazide tablets manufactured by Novartis in healthy volunteers

Public title
Bio equivalence study of Hydrochlorothiazide 50 mg tablets
Purpose
Other
Inclusion/Exclusion criteria
Inclusion criteria:
Healthy liver Healthy Kidney Observing BMI Age range between 18 and 50 years Male and female
Exclusion criteria:
Smoking Pregnancy
Age
From **18 years** old to **50 years** old
Gender
Both

Phase
Bioequivalence
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **24**
Randomization (investigator's opinion)
Randomized
Randomization description
One number from 1 to 24 will be allocated to each healthy volunteers. Then Extraction of 12 numbers (from 1 to 24) is carried out using https://kitset.ir/numbers/random#random-number-form. These first 12 random numbers create the first group.
Blinding (investigator's opinion)
Double blinded
Blinding description
The main investigator divides 24 healthy volunteers in two groups, which each group includes twelve subjects. This process is performed using randomization method. In this study, just the main investigator is not blind. Test and reference drugs are packaged in special envelops that administrator and volunteers are all blinded regarding to the reference and test (generic) drug products.
Placebo
Not used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran University of Medical Sciences
Street address
No. 65, Razi Ave, Enghelab Ave
City
Tehran
Province
Tehran
Postal code
1133713144
Approval date
2021-10-05, 1400/07/13
Ethics committee reference number
IR.IUMS.REC.1400.624

Health conditions studied

1

Description of health condition studied
Bioequivalance Hydrochlorothiazide 50 mg
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Maximum Plasma Concentration (Cmax): after drug administration, gradually the plasma concentrations increase to Cmax. After Cmax, the plasma concentrations decrease regarding to drug elimination phenomena
Timepoint
0, 0.5, 1, 1.33, 1.67, 2, 2.33, 2.67, 3, 3.5, 4, 5, 6, 8, 10 and 24 hours after intervention
Method of measurement
High performance liquid chromatography

2

Description
Tmax: the time after drug administration take to reach drug plasma concentration to Cmax.
Timepoint
0, 0.5, 1, 1.33, 1.67, 2, 2.33, 2.67, 3, 3.5, 4, 5, 6, 8, 10 and 24 hours after intervention
Method of measurement
High performance liquid chromatography

3

Description
Area under curve (AUC): AUC is obtained by plotting the plasma concentrations against corresponding times.
Timepoint
0, 0.5, 1, 1.33, 1.67, 2, 2.33, 2.67, 3, 3.5, 4, 5, 6, 8, 10 and 24 hours after intervention
Method of measurement
High performance liquid chromatography

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: One Hydrochlorothiazide 50 mg tablet manufactured by Fatak Chime Pars company (Test drug) is administrated to each of 12 healthy volunteers of group 1. Washout period is one week.
Category
Behavior

2

Description
Control group: 2 Hydrochlorothiazide 25 mg tablet manufactured by NOVARTIS company is administrated to each of 12 healthy volunteers of group 2.
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Ofoq Pharmed
Full name of responsible person
Dr Amir Mehdizadeh
Street address
Unit 14, No 65, Razi Ave, Enghelab Ave
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Fatak Chemie Pars
Full name of responsible person
Dr Reza Hadavi
Street address
No13, Second alley, Pakestan Ave, Beheshti Ave, Tehran
City
Tehran
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Tehran
Postal code
1531636319
Phone
+98 21 8873 8441
Email
info@fatakchemie.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Fatak Chemie Pars
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
Ofoqh pharmed labratory
Full name of responsible person
Dr Amir Mehdizadeh
Position
Responsible pharmacist
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
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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
Yes - There is 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
Undecided - It is not yet known if there will be 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
Demography tables of volunteers including group 1 and 2 have been shared in bioequivalance report. Volunteer data include name, sex, BMI, height and weight.
When the data will become available and for how long
The results of bioequivalance study of Hydrochlorothiazide will be shared after accepting by Iranian food and drug organization .
To whom data/document is available
The results of bioequivalance study of Hydrochlorothiazide tablets will be accessed by expert by Iranian food and drug organization and financial supporter.
Under which criteria data/document could be used
To promotion of result of investigation, the results will bi shared with eager.
From where data/document is obtainable
1- Iranian food and drug organization 2- Ofoqh pharmed research laboratory.
What processes are involved for a request to access data/document
After the completion of bio-equivalence study, Manufacturing company of generic product requests all data and document by a written letter. Generic manufacturer submits all these data to Drug Regulatory Administration to evaluate the results.
Comments