Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Nov 2026

A study to compare the relative bioavailability of Raha and AstraZeneca formulations of quetiapine 25 mg tablets in 24 healthy adult volunteers under fasting conditions

Protocol summary

Study aim
The study aims to compare the bioequivalence of quetiapin 25 mg tablets under fasting conditions

Design
This randomized, single-dose, two-way, crossover study is conducted to compare the pharmacokinetic of Quetiapine and Seroquel tablets in 24 healthy adults male volunteers. Volunteers will be sorted and receive a number from 1 to 24. In the first phase of the study, 12 volunteers will receive Quetiapine manufactured by Raha Pharmaceuticals and the remaining 12 volunteers will receive Seroquel® produced by AstraZeneca. The administered drugs will be replaced by each other in the second phase of the study. Since in this study, the volunteers will receive both Test and Reference drugs, each volunteer will act as his own control.

Settings and conduct
The dose administration and subsequent sample collection will be performed in S. Motahhari hospital (Gonbade Kavous, Iran).

Participants/Inclusion and exclusion criteria
Males, 18-50 years of age. The subject is available for the entire study period and is willing to adhere to protocol requirements as evidenced by written informed consent. The subject has stable residence and telephone. Good health at screening. Exclusion criteria: History of any drug hypersensitivity or intolerance Significant history or current evidence of chronic disease Receipt of any drug as part of a research study within 30 days prior to the present study.Donation or significant loss of whole blood (480 ml or more) within 30 days prior to the present study.

Intervention groups
A single oral dose of quetiapine 25 mg tablets manufactured by Raha and AstraZeneca companies

Main outcome variables
Drug plasma concentration; Area under the plasma concentration-time curve

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130626013776N9**
Registration date: **2018-12-02, 1397/09/11**
Registration timing: **retrospective**

Last update: **2018-12-02, 1397/09/11**
Update count: **0**

Registration date
2018-12-02, 1397/09/11

Registrant information

Name
Hossein Amini

Name of organization / entity
Golestan University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 17 1442 1651

Email address
hamini@sbmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-08-31, 1397/06/09

Expected recruitment end date
2018-10-31, 1397/08/09

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A study to compare the relative bioavailability of Raha and AstraZeneca formulations of quetiapine 25 mg tablets in 24 healthy adult volunteers under fasting conditions

Public title

Bioequivalence study of quetiapine 25 mg tablets under fasting conditions

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Males, 18-50 years of age. The subject is able and willing to provide signed informed consent. The subject is available for the entire study period and is willing to adhere to protocol requirements as evidenced by written informed consent. The subject has stable residence and telephone. Good health as determined by lack of clinically significant abnormalities in health assessments performed at screening.

Exclusion criteria:

History of allergy or sensitivity to quetiapine. History of any drug hypersensitivity or intolerance which, in the opinion of the investigator,would compromise the safety of the subject of the study. Significant history or current evidence of chronic infectious disease, system disorder or organ dysfunction. Presence of gastrointestinal disease or history of malabsorption within the last year. History of a medical disorders occurring within the last year that required hospitalization or medication Use of pharmacologic agents known to significantly induce or inhibit drug-metabolizing enzymes within 30 days prior to dosing. Receipt of any drug as part of a research study within 30 days prior to the present study. Donation or significant loss of whole blood (480 ml or more) within 30 days prior to the present study.

Age

From **18 years** old to **50 years** old

Gender

Male

Phase

Bioequivalence

Groups that have been masked

No information

Sample size

Target sample size: **24**

Randomization (investigator's opinion)

Randomized

Randomization description

According to the crossover design of the study, the twenty four participants randomized into two sequences of Test/Reference and Reference/Test products using command of rand in the Excel program.

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 Golestan University of Medical Sciences

Street address

Falsafi Building, Sari Road Km 2, Gorgan

City

Gorgan

Province

Golestan

Postal code

4916817693

Approval date

2018-09-16, 1397/06/25

Ethics committee reference number

IR.GOUMS.REC.1397.110

Health conditions studied

1

Description of health condition studied

.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Drug plasma concentration

Timepoint

At time zero and 0.25, 0.5, 0.75, 1, 1.5, 2, 2.5, 3, 4, 6, 8, 10 and 12 h after drug administration

Method of measurement

Blood sampling and measurement of drug concentrations by HPLC

2

Description

Area under plasma concentration-time curve

Timepoint

Before intervention and 0.25, 0.5, 0.75, 1, 1.5, 2, 2.5, 3, 4, 6, 8, 10 and 12 h after drug administration

Method of measurement

Blood sampling and measurement of drug concentrations by HPLC

Secondary outcomes

1

Description
Time to reach Cmax
Timepoint
During 2 hours after drug administration
Method of measurement
Blood sampling and drug analysis by HPLC

2

Description
Plasma half-life
Timepoint
From the terminal 6 hours of plasma concentration-time profile
Method of measurement
Blood sampling and drug analysis by HPLC

Intervention groups

1

Description
Intervention group: Oral administration of a single dose of quetiapine 25 mg tablet manufactured by Raha Pharmaceuticals to healthy volunteers
Category
Treatment - Drugs

2

Description
Intervention group: Oral administration of a single dose of Seroquel 25 mg tablet manufactured by AstraZeneca Co. to healthy volunteers
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Dialysis Center, S. Motahhari Hospital
Full name of responsible person
Yahya Naserifard
Street address
Taleghani Street
City
Gonbade Kavous
Province
Golestan
Postal code
4916817693
Phone
+98 17 3252 5972
Fax
+98 17 3252 5972
Email
haminhplc@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Raha Pharmaceuticals
Full name of responsible person
Dr. Akram Sharifian
Street address
Central Office:No.11, Sofeh Ind. Zone, 7th km of Shiraz Road
City
Isfehan
Province
Isfehan
Postal code
81745-567
Phone
+98 31 3654 0659
Fax
+98 31 3654 0183
Email
info@rahapharma.com
Web page address
http://rahapharm.com/home
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Raha Pharmaceuticals
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
Gorgan University of Medical Sciences
Full name of responsible person
Hossein Amini
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address

Sari Road, Km 2
City
Gorgan
Province
Golestan
Postal code
4916817693
Phone
+98 17 3252 5972
Fax
+98 17 3252 5972
Email
haminhplc@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Gorgan University of Medical Sciences
Full name of responsible person
Hossein Amini
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
Sari Road, Km 2
City
Gorgan
Province
Golestan
Postal code
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Phone
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Fax
+98 17 3252 5972
Email
haminhplc@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Gorgan University of Medical Sciences
Full name of responsible person
Hossein Amini
Position
Associate professor
Latest degree
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Other areas of specialty/work
Medical Pharmacy
Street address
Sari Road, Km 2
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Province
Golestan
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4916817693
Phone
+98 17 3252 5972
Fax
+98 17 3252 5972
Email
haminhplc@yahoo.com

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
Data are confidential and need permission from the company.
Study Protocol
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be 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
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