Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jun 2026

Comparative bioequivalence study of sodium zirconium cyclosilicate (SZC-9) in the forms of 5 and 10 g sachets vs brand medicine (Lokelma made by AztraZeneca)

Protocol summary

Study aim
Synthesis of sodium zirconium cyclosilicate (SZC-9) drug by different methods and its in vitro comparison with the brand sample available in the market (Lokelma).

Design
A clinical trial with 2 parallel intervention groups and no control group, double-blind, phase 2, on 48 patients and randomized by using the website QuickCalcs.

Settings and conduct
This study will be conducted on two series of patient volunteers. The first group will receive a sample sachet (test) and the second group will receive a brand sachet. Blood samples are taken by the clinical supervisor immediately after taking the drug, and the sample preparation steps are performed on them to analyze the amount of analyte. This study will be conducted in Imam Reza Hospital, Tabriz.

Participants/Inclusion and exclusion criteria
Patients volunteers with hyperkalaemia, both sexes, ages ranged from 22 to 75 years, para-clinical health based on the tests performed, and no history of diseases affecting the digestive system.

Intervention groups
The intervention group received single-dose SZC-9 sachet formulated in this study and the control group received single-dose brand tablets (Lokelma®) manufactured by the company (AstraZeneca).

Main outcome variables
Level of blood potassium concentration

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130313012810N11**
Registration date: **2023-07-15, 1402/04/24**
Registration timing: **prospective**

Last update: **2023-07-15, 1402/04/24**
Update count: **0**

Registration date
2023-07-15, 1402/04/24

Registrant information
Name
Hamed Hamishehkar
Name of organization / entity
Drug Applied Research Center, Tabriz University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 41 1336 3311
Email address
hamishehkar.hamed@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-08-31, 1403/06/10

Expected recruitment end date
2024-10-31, 1403/08/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparative bioequivalence study of sodium zirconium cyclosilicate (SZC-9) in the forms of 5 and 10 g sachets vs brand medicine (Lokelma made by AztraZeneca)

Public title
Comparative bioequivalence study of sodium zirconium cyclosilicate (SZC-9) in the forms of 5 and 10 g sachets vs brand medicine (Lokelma made by AztraZeneca)
Purpose
Other
Inclusion/Exclusion criteria
Inclusion criteria:
patients with hyperkalemia Volunteers aged 22-75 years male and female
Exclusion criteria:
History of diseases affecting the digestive system Taking any medication at least 1 week before the start of the study
Age
From **22 years** old to **75 years** old
Gender
Both

Phase
Bioequivalence
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **24**
Randomization (investigator's opinion)
Randomized
Randomization description
Web-based randomization is used by using the website http://www.graphpad.com/quickcalcs/index.cfm Candidates will be given codes 1 to 48 in the order of entering the study, so that when the selection of candidates begins, the first person who enters the study will have code 1 and the last candidate who enters the study will have code 48. Then the following steps will be done on the site: Random numbers>>>Randomly assign subjects to groups>>>Randomly choose a group for each subject. And finally, two groups A and B will be randomly composed of 24 volunteers each.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, the volunteers participating in the study and the clinical supervisor are blinded to the type of product consumed at each time of the study (test or reference product). That is, the product outside the original packaging will be given to the volunteer by the researcher for consumption
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences
Street address
Daneshghah St. Drug Applied Research Center
City
Tabriz
Province
East Azarbaijan
Postal code
5165665811
Approval date
2023-03-06, 1401/12/15
Ethics committee reference number
IR.TBZMED.REC.1401.1098

Health conditions studied

1

Description of health condition studied
Hyperkalaemia
ICD-10 code
E87.5
ICD-10 code description
Hyperkalaemia

Primary outcomes

1

Description
Plasma concentration of potassium
Timepoint
Measurement of blood potassium at the beginning of the study (before the start of the intervention), 2, 6, 12, 24, 36, and 48 hours after receiving the drug by the patients
Method of measurement
Biorexfars potassium kit

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Candidates will receive 10 grams of powder (sachet) of the test drug and blood will be taken 48 hours after receiving the drug
Category
N/A

2

Description
Intervention group 2: Candidates will receive 10 grams of

powder (sachet) of the brand drug and blood will be taken 48 hours after receiving the drug

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Drug Applied Research Center, Tabriz University of Medical Sciences

Full name of responsible person

Hamed Hamishehkar

Street address

Drug Applied Research Center, Tabriz University of Medical Sciences

City

Tabriz

Province

East Azarbaijan

Postal code

51656-65811

Phone

+98 41 3336 3311

Email

hamishehkar.hamed@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Parviz Shahabi

Street address

Research and Technology Vice-Chancellor., Central Building No. 2., 3rd Floor.,Tabriz University of Medical Sciences., Golgasht Street

City

Tabriz

Province

East Azarbaijan

Postal code

5165990001

Phone

+98 41 3336 4664

Email

shahabip@tbzmed.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tabriz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Hamed Hamishehkar

Position

professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Drug Applied Research Center, Tabriz University of Medical Sciences

City

Tabriz

Province

East Azarbaijan

Postal code

51656-65811

Phone

+98 41 3336 3181

Fax

+98 41 3336 3311

Email

hamishehkar.hamed@gmail.com

Web page address

http://darc.tbzmed.ac.ir/

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Hamed Hamishehkar

Position

professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Drug Applied Research Center, Tabriz University of Medical Sciences

City

Tabriz

Province

East Azarbaijan

Postal code

51656-65811

Phone
+98 41 3336 3181

Fax
+98 41 3336 3311

Email
hamishehkar.hamed@gmail.com

Web page address
http://darc.tbzmed.ac.ir/

Person responsible for updating data

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Hamed Hamishehkar

Position
professor

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

Street address
Drug Applied Research Center, Tabriz University of Medical Sciences

City
Tabriz

Province
East Azarbaijan

Postal code
51656-65811

Phone
+98 41 3336 3181

Fax
+98 41 3336 3311

Email
hamishehkar.hamed@gmail.com

Web page address
http://darc.tbzmed.ac.ir/

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

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