Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of discontinuation of angiotensin-II receptor blocker on therapeutic effect of synthetic erythropoietin on anemia modification in hemodialysis patients

Protocol summary

Study aim
evaluate the effect of discontinuation of losartan in response to synthetic erythropoietin therapy on hemoglobin level in hemodialysis patients

Design
Clinical trial; pre- and post-treatment

Settings and conduct
The population of this study is hemodialysis patients with end stage renal disease who referred to Mashhad academic hospitals in 1397. After observing the inclusion/exclusion criteria, the level of hemoglobin changes in patients before and three months after removal of losartan drug will compared.

Participants/Inclusion and exclusion criteria
All hemodialysis hypertensive patients who were treated with losartan for at least three months were included. In all patients, no changes in the dose of erythropoietin and iron as well as carnitine supplements will given from three months before and during the three-month intervention period. In addition, any serious infection (leading to hospitalization), obvious bleeding, or history of blood and its products transfusion, as well as any type of surgery, exclud from the study. ferritine level less than 100 ng/ml or CRP more than 10 mg/L will also exluded from the study. Dialysis session duration and frequencies will remined constant, otherwise will excluded.

Intervention groups
Control group: Patients who have received losartan for at least three months case group: The same patients in the control group who stopped taking losartan for 3 months

Main outcome variables
hemoglobin modification

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190127042516N1**
Registration date: **2019-02-13, 1397/11/24**
Registration timing: **registered_while_recruiting**

Last update: **2019-02-13, 1397/11/24**
Update count: **0**

Registration date
2019-02-13, 1397/11/24

Registrant information

Name
Mahmood Reza Khazaei

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 3840 1279

Email address
khazaeem@mshdiau.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-02-09, 1397/11/20

Expected recruitment end date
2019-05-22, 1398/03/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of discontinuation of angiotensin-II receptor blocker on therapeutic effect of synthetic erythropoietin

on anemia modification in hemodialysis patients

Public title
Effect of Losartan discontinuation on treatment of anemia in hemodialysis patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All hypertensive patients with ESRD on regular hemodialysis consist of 3 4-hours session per week. Use of Losartan at least the last three months
Exclusion criteria:
Dosage alteration for rHuEPO, ferrous sulfate and Carnitine supplementation. Serious infection leading hospitalization Obvious bleeding Transfusion Surgery CRP>10 mg/L Serum Ferritin <100 ng/ml Any alteration in hemodialysis dosage/time
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **28**
More than 1 sample in each individual
Number of samples in each individual: **2**
Two samples are taken from each person. The first stage was immediately before the discontinuation of the drug (as the control group) and the second one, 3 months after the discontinuation (as the case group)
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features
This research is a clinical trial and pre- and post-intervention method. The duration of the intervention is three months. The values of the relevant variable (hemoglobin level) before the treatment intervention (control group) will compared with the values after the discontinuation of the drug (test group). Immediately prior to discontinuing and replacing losartan, the venous blood sample is taken as a control group for testing.The losartan will discontinued and the blood pressure will controlled with the oral antihypertensive medication other than ACE-I or ARB categories. After three months of treatment intervention, blood samples are taken again as the test group. Blood samples of 5cc from the intravenous line of vascular access are obtained immediately before hemodialysis. Blood hemoglobin level (gr / dl) is measured with Cell Counter Mindry BC 3000Plus machine.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee in bio-medicine research - Mashhad branch
Street address
Sarab Ave., Azadi st.
City
Mashhad
Province
Razavi Khorasan
Postal code
9185666773
Approval date
2018-09-05, 1397/06/14
Ethics committee reference number
IR.IAU.MSHD.REC.1397.028

Health conditions studied

1

Description of health condition studied
Hypertensive heart and chronic kidney disease without heart failure, with stage 5 chronic kidney disease, or end stage renal disease
ICD-10 code
I13.11
ICD-10 code description
Hypertensive heart and chronic kidney disease without heart failure, with stage 5 chronic kidney disease, or end stage renal disease

Primary outcomes

1

Description
Hemoglobin increment
Timepoint
Before intervention and 3 months after discontinuation of Losartan
Method of measurement
Cell Counter Mindry BC 3000Plus machine

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Discontinuation of Losartan

Category
Treatment - Drugs

2

Description
Control group: Hemodialysis patients on Losartan for at least 3 months
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
22 Bahman hospital
Full name of responsible person
Mahmood Reza Khazaei
Street address
Telgerd, Golshahr
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Razavi Khorasan
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91577 94985
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Abtahi Saeed
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Sarab Ave., Azadi St.
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sabtahimd@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Personal cost
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
Islamic Azad University
Full name of responsible person
Mahmood Reza Khazaei
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics
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Person responsible for updating data

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Associate professor

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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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is 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

Demographic information and the results of the main outcome after unidentifiable patients can be shared.

When the data will become available and for how long

Six months after the publication of the results and with an official request

To whom data/document is available

All nephrologists working in research institutes and universities

Under which criteria data/document could be used

Use of data is subject to observance of intellectual property rights of the researcher

From where data/document is obtainable

khazaeem@yahoo.com

What processes are involved for a request to access data/document

Maximum one month after receipt of the request.

Comments