

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

Investigating the effect of resveratrol on therapeutic outcomes of acute ischemic stroke patient receiving r-tPA

Protocol summary

Study aim

Evaluation of the effect of resveratrol on the outcome of patients with acute stroke who received r-tPA.

Design

A randomized controlled clinical trial with parallel, double-blind, randomized groups

Settings and conduct

This study is conducted at Imam Reza Hospital in Kermanshah. The research area is related to stroke and is done by block randomization method with a block size of 4 which is detailed in the previous section. After random selection of participants (patients), in order to secrete (hide) the given treatment type from groups, the studied drugs will be made identical in appearance (1st level of blinding), and for blinding the doctor, the drugs are prepacked in packets marked as packet A and B. Then in the final step, depending on the assigned code (A or B) given to the patient, the related treatment will be given to the participant.

Participants/Inclusion and exclusion criteria

Inclusion criteria include patient satisfaction and patient companions who received r-tPA. Exclusion criteria include pregnant patients or people under 18 and over 90 years or patients who have received r-tPA for more than 24 hours.

Intervention groups

Intervention group: Resveratrol control group: placebo

Main outcome variables

Reduction of bleeding caused by clotting agent as well as beneficial effects in the treatment of stroke

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191020045162N1**

Registration date: **2020-03-12, 1398/12/22**

Registration timing: **registered_while_recruiting**

Last update: **2020-03-12, 1398/12/22**

Update count: **0**

Registration date

2020-03-12, 1398/12/22

Registrant information

Name

Dalir Parsa

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 83 3427 6321

Email address

drdparsa68@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-11, 1398/08/20

Expected recruitment end date

2021-01-09, 1399/10/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of resveratrol on therapeutic outcomes of acute ischemic stroke patient receiving r-tPA

Public title

The effect of resveratrol on stroke

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All of acute ischemic stroke patient receiving r-tPA.

Exclusion criteria:

Pregnant patient Patients who received r-tPA more than 24 hours ago Previous cerebral hemorrhage and previous stroke

Age

From **18 years** old to **90 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, block randomization method is used since patients go to the doctors over time, and we aim to have both studied groups receive equal treatment. To do so, we use a block size of 4 and for the sample size of 40 a block size of 4 will be generated. Then, in the next step, beside block randomization, each generated random sequence will be written on a separate card and placed in non-transparent blocks, like block number 1 sequence AABB. They are used based on numerical orders allocated to each block, and block sequence for the studied patients is used. This procedure will be carried out till the end of the study. In order to use the random allocation method, a methodologist places the blocks in sequence, handles the blocking and numbering process according to the required sample size, and shares them with the related department's receptionist who is not aware of the studied treatments. Then he/she informs the patients the purpose of this study and investigates the input and output criteria of the study. In the final step, the patients will be assigned to the related studied group by receiving a code from the receptionist and will be referred to a doctor.

Blinding (investigator's opinion)

Double blinded

Blinding description

After a random selection of patients To hide groups receiving treatment, the capsule understudy will be similar in shape (First level blinding) and to blind the therapist, Drugs are prepackaged in envelopes marked A and B and depending on which code the patient goes to see a doctor will receive the desired treatment.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of kermanshah university of medical sciences

Street address

Nursing Blvd - Imam reza hospital

City

kermanshah

Province

Kermanshah

Postal code

6714415333

Approval date

2019-10-20, 1398/07/28

Ethics committee reference number

IR.KUMS.REC.1398.718

Health conditions studied

1

Description of health condition studied

Ischemic stroke

ICD-10 code

I67

ICD-10 code description

Other cerebrovascular diseases

Primary outcomes

1

Description

NIHSS : National Institutes of Health Stroke Scale

Timepoint

Symptoms onset - 24 hours later - discharge time

Method of measurement

Using a checklist and a special form that will be filled in according to the patient's history and examination.

2

Description

Modified Rankin Scale (MRS)

Timepoint

Before symptoms begin - three months later

Method of measurement

Based on specific forms that the patient or his / her companions will be asked to telephone or in person.

3

Description

Barthel Index

Timepoint

Three months later

Method of measurement

Based on specific forms that the patient or his / her companions will be asked by phone or in person.

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Patients with stroke receiving r-tPA who receive oral resveratrol capsule (150 mg every eight hours) and herbal medicine purchased from overseas and Packaged by pharmacists at Kermanshah School of Pharmacy.

Category

Treatment - Drugs

2**Description**

Control group: Patients with stroke receiving r-tPA who receive placebo(Lactulose oral capsule every eight hours) and Packaged by pharmacists at Kermanshah School of Pharmacy.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam reza hospital

Full name of responsible person

Payam Sari aslani

Street address

Parastar blv - Imam reza hospital

City

Kermanshah

Province

Kermanshah

Postal code

6714415333

Phone

+98 83 3427 6303

Email

drdparsa68@gmail.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Kermanshah University of Medical Sciences

Full name of responsible person

Payam Sari aslani

Street address

Parastar blvd - Imam reza hospital

City

Kermanshah

Province

Kermanshah

Postal code

6714415333

Phone

+98 83 3427 6303

Email

drdparsa68@gmail.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Kermanshah 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**

Kermanshah University of Medical Sciences

Full name of responsible person

Payam Sariaslani

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Neurology

Street address

Parsatar Blvd, Imam Reza Hospital

City

Kermanshah

Province

Kermanshah

Postal code

6714415333

Phone

+98 83 3427 6303

Email

drdparsa68@gmail.com

Person responsible for scientific

inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Payam Sariaslani

Position

Assistant professor

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Other areas of specialty/work

Neurology

Street address

Parsatar Blvd, Imam Reza Hospital

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Phone

+98 83 3427 6303

Email

drdparsa68@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Payam Sariaslani

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Neurology

Street address

Parastar Blvd, Imam Reza Hospital

City

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Email

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

The amount of changes in MRS and Bartel index in the two groups

When the data will become available and for how long

6 month after publishing article

To whom data/document is available

For the public

Under which criteria data/document could be used

For further research

From where data/document is obtainable

Imam Reza Hospital Kermanshah - Dr. Payam Sariaslani

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

Applying to the hospital and Dr. Sariaslani will then announce the outcome.

Comments