# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 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 reciving 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 siences

**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
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## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Kermanshah University of Medical Sciences
**Full name of responsible person**
Payam Sari aslani
**Street address**
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**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**
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## Person responsible for scientific

## inquiries

**Contact**

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Kermanshah University of Medical Sciences
**Full name of responsible person**
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**Position**
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## Person responsible for updating data

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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**