

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of ozone therapy and routine medical treatment efficacy on serum level changes of TNF- α and CRP as well as neurological improvement in recovery period in patients with ischemic stroke

Protocol summary

Study aim

Comparison of ozone therapy and routine medical treatment efficacy on serum level changes of TNF- α and CRP as well as neurological improvement in recovery period in patients with ischemic stroke

Design

Clinical trial with control group, with parallel and non-randomized groups

Settings and conduct

This study is an Interventional study and will be done in Ayatollah Yasrib hospital in Kashan in year 97 on 72 stroke patients referred to hospital emergency department.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Being in the phase of rehabilitation of ischemic stroke (NIHSS <15-mRs <5) and being alert to cooperate in the implementation of the plan 2- At least 2 months have passed since the onset of acute stroke Exclusion criteria: 1. Hemorrhagic stroke 2. Cancer 3. Active infection

Intervention groups

Thirty-six patients in the first group (control group) will receive medication and receive physiotherapy, and 36 patients in the second group (intervention group) will benefit from ozone therapy in addition to the measures mentioned above.

Main outcome variables

TNF- α , recurrent stroke, CRP, disease severity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200202046342N1**

Registration date: **2020-03-03, 1398/12/13**

Registration timing: **retrospective**

Last update: **2020-03-03, 1398/12/13**

Update count: **0**

Registration date

2020-03-03, 1398/12/13

Registrant information

Name

Seyed Hadi hoseinipour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5550 0111

Email address

hoseinipour-sh@mail.kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-22, 1397/09/01

Expected recruitment end date

2019-01-21, 1397/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of ozone therapy and routine medical treatment efficacy on serum level changes of TNF- α and CRP as well as neurological improvement in recovery period in patients with ischemic stroke

Public title

Ozone therapy and routine medical treatment efficacy on serum level changes of TNF- α and CRP as well as

neurological improvement

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Being in the phase of ischemic stroke rehabilitation (NIHSS <15- mRS <5) and being alert to cooperate in the implementation of the plan At least 2 months have passed since the onset of acute stroke
Exclusion criteria:
Hemorrhagic stroke Cancer Active infection

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: 72

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Kashan university of medical sciences, Qotbe Ravandi Blvd, Kashan

Street address

Kashan university of medical sciences, Qotbe Ravandi Blvd, Kashan

City

Kashan

Province

Isfahan

Postal code

8711111111

Approval date

2018-10-29, 1397/08/07

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1397.57

Health conditions studied

1

Description of health condition studied

Ischemic stroke

ICD-10 code

I63.9

ICD-10 code description

Transient cerebral ischemic attacks and related syndromes

Primary outcomes

1

Description

Serum levels of TNF- α and hs-CRP

Timepoint

Patients in the first group (control group) will receive the medication on the first day and will receive physiotherapy. After 90 days, serum levels of TNF- α and hs-CRP were also determined by ELISA.

Method of measurement

Serum TNF- α and hs-CRP levels were also determined by ELISA.

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Receive normal medicine. Serum levels of TNF- α and hs-CRP will also be determined by ELISA with the US-based kit ELISA by eBioscience Iranian company Amines.

Category

Treatment - Drugs

2

Description

Intervention group: receive normal medical plus ozone therapy. Ozone therapy is performed in accordance with the standard protocol of major chemotherapy. Serum levels of TNF- α and hs-CRP will also be determined by ELISA with the US-based kit ELISA by eBioscience Iranian company Amines.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Yasrabi Hospital of Kashan

Full name of responsible person

hoseinipour seyed Hadi

Street address

Kashan university of medical sciences, Qotbe Ravandi
Blvd, Kashan

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Phone

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Email

hoseinipour-sh@mail.kaums.ac.ir

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Fax**Email**

hoseinipour-sh@mail.kaums.ac.ir

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Kashan University of Medical Sciences

Full name of responsible person

hoseinipour seyed Hadi

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Email

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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

Kashan 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**

Kashan University of Medical Sciences

Full name of responsible person

Seyed Hadi Hoseinipour

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Kashan University of Medical Sciences

Full name of responsible person

Mehdi Kheiran

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

General Practitioner

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Person responsible for updating data

Contact**Name of organization / entity**

Kashan University of Medical Sciences

Full name of responsible person

Seyed Hadi Hoseinipour

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

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Fax**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

Not applicable

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

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

Part of the data can be shared.

When the data will become available and for how long

After printing the article

To whom data/document is available

researchers

Under which criteria data/document could be used

For more extensive study

From where data/document is obtainable

Email to responsible author

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

Written request by email

Comments