

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Effects of Anti-CD20 monoclonal antibody on immunologic factors in elderly patients with ischemic stroke

Protocol summary

Study aim

Effects of Anti-CD20 monoclonal antibody on immunologic factors in elderly patients with ischemic stroke

Design

This study is an interventional study in elderly people with ischemic stroke. The subjects included an ischemic stroke group who received monoclonal antibodies against the CD20 antigen and control group that did not receive this antibody.

Settings and conduct

Patients who are determined by a neurologist specialist will be referred to the person responsible for the research. After 24 hours of acute phase of stroke in the fasting, 8 cc of venous blood will be taken from each person. In this project, the frequency of B cells as well as inflammatory cells Th1 and Th17 cells and related factors include T-bet transcription factors, ROR γ t, IFN- γ , TNF- α and IL-17, IL-23 cytokines will be examined in both of groups and compared. The volume of brain damaged tissue is also evaluated by the neurologist and using the MRI technique.

Participants/Inclusion and exclusion criteria

Elderly people with ischemic stroke are determined to be clinically diagnosed with CT scans by a neurologist specialist will be referred to the person responsible for the research. Patients who have evidence of acute or chronic intracerebral hemorrhage, neoplasm or cerebral aneurysms are excluded.

Intervention groups

An interventional group of elderly people with ischemic stroke who receives anti-CD20 monoclonal antibody. The control group is elderly with ischemic stroke, who does not receive anti-CD20 monoclonal antibody.

Main outcome variables

The frequency of CD20 + B cells
The frequency of Th1 and Th17 cells
The gene expression of effective transcription factors and cytokines from Th1 and Th17 cells
The secretion levels of this cytokines

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160422027520N11**

Registration date: **2019-03-07, 1397/12/16**

Registration timing: **prospective**

Last update: **2019-03-07, 1397/12/16**

Update count: **0**

Registration date

2019-03-07, 1397/12/16

Registrant information

Name

Mehdi Yousefi

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-20, 1398/02/30

Expected recruitment end date

2019-08-21, 1398/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Anti-CD20 monoclonal antibody on immunologic factors in elderly patients with ischemic stroke

Public title

Treatment of elderly patients with ischemic stroke

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Willingness to cooperate Aged 60 to 75 years Diagnosis of ischemic stroke by a neurologist Radiological findings (MRI, CT) consistent with clinical diagnosis of ischemic stroke NIHSS score between 6 and 22

Exclusion criteria:

Use of nutritional supplements and antioxidant and alpha-lipoic acid during a month before the study History of diabetes, high or low blood pressure and other chronic diseases (kidney, lung disorders, etc.), anemia, thrombocytopenia A history of autoimmune diseases, immunodeficiency diseases, asthma and allergies Cancer Viral infections (hepatitis B, influenza ...) Occurrence of recurrence of disease during the study Evidence from CT or MRI based on acute or chronic intracerebral hemorrhage, arteriovenous malformation (AVM), Subarachnoid hemorrhage (SAH) brain aneurysm or tumor. Symptoms or signs of neurology that quickly recover during screening and are likely to recover completely within 24 hours. Not wanting to continue cooperation

Age

From **60 years** old to **75 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **12**

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

Ethics committee of Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences , Daneshgah st, Tabriz,

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Tabriz

Province

East Azarbaijan

Postal code

5166616471

Approval date

2018-12-03, 1397/09/12

Ethics committee reference number

IR.TBZMED.REC.1397.709

Health conditions studied

1

Description of health condition studied

Elderly patients with ischemic stroke

ICD-10 code

I63.9

ICD-10 code description

Ischemic Stroke

Primary outcomes

1

Description

Determination of Frequency of CD20 + B Cells in Elderly People with Ischemic Stroke in the Group Receiving Anti-CD20 Antibody and Control Group

Timepoint

After 24 hours of stroke in acute phase

Method of measurement

Flow cytometry

2

Description

Determination of the frequency of Th1 and Th17 cells in the elderly with ischemic stroke in the group receiving Anti-CD20 Antibody and Control Group

Timepoint

After 24 hours of stroke in acute phase

Method of measurement

Flow cytometry

3

Description

Determination of the expression of gene expression of effective transcription factors in the development of Th1 and Th17 cells in the elderly with ischemic stroke in the group receiving Anti-CD20 Antibody and Control Group

Timepoint

After 24 hours of stroke in acute phase

Method of measurement

Quantitative Real time PCR

4

Description

Determination of the expression of cytokine genes from Th1 and Th17 cells in the elderly with ischemic stroke in the group receiving Anti-CD20 Antibody and Control Group

Timepoint

After 24 hours of stroke in acute phase

Method of measurement

Quantitative Real time PCR

5

Description

Determination of the secretion of cytokines secreted from Th1 and Th17 cells in the elderly with ischemic stroke in the group receiving Anti-CD20 Antibody and Control Group

Timepoint

After 24 hours of stroke in acute phase

Method of measurement

Quantitative Real time PCR

Secondary outcomes

1

Description

Determination of infarction brain tissue in elderly patients with ischemic stroke in the group receiving monoclonal antibodies anti-antigen CD20 and control group

Timepoint

One month after receiving the drug

Method of measurement

MRI,CT scan

Intervention groups

1

Description

Intervention group: Elderly patients with ischemic stroke who received the anti-CD20 monoclonal antibody

Category

Treatment - Drugs

2

Description

Control group: Elderly people with ischemic stroke are not receiving the anti-CD20 monoclonal antibody

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Mehdi Yousefi

Street address

Imam Reza Hospital , Golgasht Avenue , Tabriz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

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

Mehdi Yousefi

Position

Ph.D Of Medical Immunology / Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Immunology

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Person responsible for updating data

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Other areas of specialty/work

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Fax

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