Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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, RORγt, 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 anorsiums 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

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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 , Daneshghah st, Tabriz,
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Tabriz
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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
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Imam Reza Hospital , Golgasht Avenue , Tabriz
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Sponsors / Funding sources

1

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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
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Other areas of specialty/work
Immunology
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Person responsible for updating data

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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