Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effect of combined exercises (stretching, voluntary balance coordination, aerobic, resistance) along with soy milk supplement on performance, trunk -control-movement, daily life activities, electrolyte balance, ischemic lesion volume and cognitive complication in stroke patients.

Protocol summary

Study aim
Determining the effect of combined sports exercises (stretching, voluntary balance coordination, aerobics, resistance) along with milk supplement on the complications mentioned in the title in stroke patients

Design
1:1:1:1 four phases: control (received hospital routine activity) [CG], training group (received combined exercise training) [TG], training + supplement group (received combined exercise training + soy milk supplement) [TS] And the supplement group (receiving routine hospital activity + soy milk supplement) [SG] will be homogenized based on age, sex, and lesion level. Randomization: RASS software Sample size: 120 people according to the pilot study: 30 people for each group

Settings and conduct
Place of intervention: Imam Reza Hospital Stretching, resistance, aerobic, balance exercises will be performed for patients.

Participants/Inclusion and exclusion criteria
Diagnosis of stroke by physician, consciousness level 14 to 16 based on Four Score, NIHSS score 5-15 (National Institutes of Health Stroke Scale), no TPA, no aphasia (based on (NIHSS criteria, stable vital signs) systolic blood pressure above 90 mmHg, heart rate above 40 and oxygen saturation above 94%)r the wrist

Intervention groups
Control (received hospital routine activity) [CG], training group (received combined sports exercises) [TG], training + supplement group (received combined sports exercises + soy milk supplement) [TS] and supplement group (received hospital routine activities + supplement Soy milk [SG]

Main outcome variables
Ability to move, balance, electrolyte changes, volume of ischemic lesion, cognitive status, trunk control

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130816014371N3**
Registration date: **2022-12-09, 1401/09/18**
Registration timing: **prospective**

Last update: **2022-12-09, 1401/09/18**
Update count: **0**

Registration date
2022-12-09, 1401/09/18

Registrant information

Name
Vahid Sari-Sarraf

Name of organization / entity
University of Tabriz

Country
Iran (Islamic Republic of)

Phone
+98 41 3339 3254

Email address
sarraf@tabrizu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-12-15, 1401/09/24

Expected recruitment end date
2023-01-19, 1401/10/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of combined exercises (stretching, voluntary balance coordination, aerobic, resistance) along with soy milk supplement on performance, trunk -control-movement, daily life activities, electrolyte balance, ischemic lesion volume and cognitive complication in stroke patients.

Public title
Effect of combined exercises (stretching, voluntary balance coordination, aerobic, resistance) along with soy milk supplement on performance, trunk -control-movement, daily life activities, electrolyte balance, ischemic lesion volume and cognitive complication in stroke patients.

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Diagnosis of stroke by physician consciousness level 14 to 16 based on Four Score NIHSS score 5-15 (National Institutes of Health Stroke Scale) no TPA no aphasia (based on (NIHSS criteria, stable vital signs) systolic blood pressure above 90 mmHg, heart rate above 40 and oxygen saturation above 94%) absence of significant fractures and orthopedic defects in organs absence of acute coronary syndrome respiratory failure or heart failure based on hospital records absence of conditions life-threatening such as having cardiac arrhythmia or receiving inotrope drugs (dopamine, dobuitamin) absence of restriction of movement so that the participant can raise his hand to the table paresis or unilateral body paralysis inactive range of motion at least 90 degrees for abduction shoulder and elbow flexion and 30 degrees for the wrist

Exclusion criteria:
Overt heart disease such as heart failure, angina pectoris, myocardial infarction within 120 days prior to the intervention, cardiomyopathy, or severe cardiac arrhythmia inflammation or infection muscular dystrophy, myasthenia gravis

Age
From **25 years** old to **65 years** old

Gender
Both

Phase
4

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description
The random sequence of allocation by a person not involved in the research using RAS (Random Allocation Software) and random block design using blocks of three and six for allocation in three groups: intervention group 1, intervention group 2 and control (production) will be done. Allocation concealment will be done based on the sequence produced by using opaque, closed and identical envelopes numbered from number 1 to the end. The first person who enters the study will be given envelope number 1 and This process will continue until the end, so the researcher and the researched person will not know the type of Allocation Concealment received until after the envelopes are opened. In this study, the patients will be the ones filling the questionnaire, the statistical analyzer and the outcome examiner will be blinded. Sufficient information about the objectives of the research and its importance is given to the participants and they are assured about the confidentiality of their personal information.

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, the patients will be the ones filling the questionnaire, the statistical analyzer and the outcome examiner will be blinded. Sufficient information about the objectives of the research and its importance is given to the participants and they are assured about the confidentiality of their personal information. Patients will not be informed about the type of exercises received, and because their hospital room is separate, they will not imitate each other's movements.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Tabriz university

Street address
Golgasht Street, Imam Reza Hospital

City
Tabriz

Province
East Azarbaijan

Postal code
5155676439

Approval date
2022-10-18, 1401/07/26

Ethics committee reference number
IR.TABRIZU.REC.1401.038

Health conditions studied

1

Description of health condition studied
STROKE
ICD-10 code
I69.4
ICD-10 code description
I69.4

Primary outcomes

1

Description
BALANCE
Timepoint
Before the intervention and 1, 2, 3, 4 weeks after the intervention
Method of measurement
through a questionnaire

2

Description
MORITCITY AND MOBILBITY
Timepoint
Before the intervention and 1, 2, 3, 4 weeks after the intervention
Method of measurement
through a questionnaire

3

Description
TRUNK CONTROL
Timepoint
Before the intervention and 1, 2, 3, 4 weeks after the intervention
Method of measurement
through a questionnaire

4

Description
Ability to perform daily tasks
Timepoint
Before the intervention and 1, 2, 3, 4 weeks after the intervention
Method of measurement
through a questionnaire

5

Description
Electrolytic changes
Timepoint
Before the intervention and 1, 2, 3, 4 weeks after the intervention
Method of measurement
through blood sample analysis

6

Description
Ischemic lesion volume and cognitive status
Timepoint
Before the intervention and 1, 2, 3, 4 weeks after the intervention: for the cognitive status and size of the lesion before and after the last intervention
Method of measurement
Through a questionnaire: cognitive status and examination of patients' scans: the size of the lesion

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Training group (receiving combined sports training) [TG],
Category
Rehabilitation

2

Description
Intervention group: Exercise group + supplement (receive combined exercise + soy milk supplement) [TS]
Category
Rehabilitation

3

Description
Intervention group: Supplement group (receiving routine hospital activity + soy milk supplement)[SG]
Category
Rehabilitation

4

Description
Control group: Control (receipt of hospital routine activity)
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
EMAM REZA HOSPITAL
Full name of responsible person
DR.VAHID SARRAF
Street address
GOLGASHT STREET
City
TABRIZ

Province
East Azarbaijan
Postal code
5155676439
Phone
+98 41 3334 7054
Email
sarraf@tabrizu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr. Vahid sarraf
Street address
Golgash
City
Tabriz
Province
East Azarbaijan
Postal code
5155676934
Phone
+98 41 3334 7054
Email
sarraf@tabrizu.ac.ir
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
30
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
dr. Vahid sarraf
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Immunology
Street address
Golgasht
City
Tabriz
Province
East Azarbaijan
Postal code
5155676934
Phone
+98 41 3334 7054
Email
sarraf@tabrizu.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr.vahid sarraf
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Immunology
Street address
Golgasht
City
Tabriz
Province
East Azarbaijan
Postal code
5155676934
Phone
+98 41 3334 7054
Email
sarraf@tabrizu.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
dr.Vahid sarraf
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Immunology
Street address
Golgasht
City
Tabriz
Province
East Azarbaijan
Postal code
5155676934
Phone

+98 41 3334 7054

Email

sarraf@tabrizu.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

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

All data is potentially shareable after de-identifying individuals.

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

All researchers

Under which criteria data/document could be used

For similar studies to consolidate the results

From where data/document is obtainable

To the responsible person's email

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

To the responsible person's email

Comments