Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Designing and determining the dosage of a treatment plan for swallowing disorder and comparing its effectiveness on swallowing function in patients following stroke in the Subacute phase

Protocol summary

Study aim

Design and determine the dosage of a treatment plan for swallowing disorders and compare its effectiveness on the swallowing function of patients following a stroke in the subacute phase.

Design

Clinical trial with three parallel groups with an allocation ratio of 1:1:1, double-blind, randomization with allocation concealment via sealed opaque envelopes, each group with 15 participants.

Settings and conduct

Participants are blinded to which group they are in and to the statistical analyst. The study will be SCU as well as the neurology departments of Rasool Akram and Imam Reza hospitals.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1) The patient must be between 20 and 80 years old 2) Ischemic stroke diagnosed by a neurologist using CT or MRI and must not have a history of stroke in the past. 3) At least two weeks have passed since the stroke occurred 4) the patient must have oropharyngeal swallowing disorder. 5) The patient must not have undergone any treatment program. 6) No cognitive impairment, dementia and Alzheimer's disease based on MOCA score ≥ 27 7) NIHSS index score ≥ 12. Exclusion criteria: 1) Severe reflux. 2) Swallowing disorder due to drug toxicity. 3) Severe restlessness and decreased consciousness. 4) Having aphasia, severe speech and comprehension disorder. 5) Recurrence of stroke during treatment

Intervention groups

The first group will undergo selected treatments (pressure swallowing, supraglottic maneuver, tongue stretching and resistance exercises) at a minimum dose (25% less than the average dose provided in the sources). second group will undergo at a medium dose (the dose recommended in reliable sources). third group will undergo at a maximum dose (25% more than the average dose provided in the sources).

Main outcome variables

Change in the total score of the (MASA) test at 4 time points (before, week 3, week 6, week 12).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220311054258N2**
Registration date: **2025-12-21, 1404/09/30**
Registration timing: **prospective**

Last update: **2025-12-21, 1404/09/30**
Update count: **0**

Registration date

2025-12-21, 1404/09/30

Registrant information

Name

mahsa mehdizadeh behtash

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-01-21, 1404/11/01

Expected recruitment end date

2027-01-21, 1405/11/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Designing and determining the dosage of a treatment plan for swallowing disorder and comparing its effectiveness on swallowing function in patients following stroke in the Subacute phase

Public title
Designing and determining the dosage of a treatment plan for swallowing disorder and comparing its effectiveness on swallowing function in patients following stroke in the Subacute phase
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
The patient age is between 20 and 80 years The patient has been diagnosed with ischemic stroke by a neurologist using CT or MRI and has no history of stroke in the past At least two weeks have passed since the stroke occurred According to the MASA test, the patient has oropharyngeal swallowing disorder The patient has not been concurrently undergoing any treatment program to improve the swallowing disorder No history of any other disease associated with swallowing disorder such as Parkinson's disease, cervical spinal cord injury, concussion, myasthenia gravis and amyotrophic lateral sclerosis, seizures, epilepsy, and multiple sclerosis No cognitive impairment, dementia, or Alzheimer's disease based on MOCA score ≥ 27 NIHSS index score ≥ 12
Exclusion criteria:
Severe reflux. Swallowing disorder due to drug toxicity. Severe restlessness and decreased consciousness. Having aphasia, severe speech and comprehension disorder (scoring a score of 4 or lower on the listening comprehension item of the Massa test and a score of 2 or lower on the aphasia item of the Massa test) Recurrence of stroke during treatment.
Age
From **20 years** old to **80 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **45**
Randomization (investigator's opinion)
Randomized
Randomization description
Block (ratio 1:1:1), with allocation concealment through sealed opaque envelopes. Allocation implementation: An independent person generates the randomization list and prepares the envelopes; the therapist opens the envelope after the participant arrives and the subjects are assigned to the groups accordingly. This is a double-blind study and the blinding is as follows: Participants are not aware of the nature of the dose differences and their group; Visits are scheduled so that participants in different groups do not meet each other.
Blinding (investigator's opinion)
Double blinded
Blinding description
This is a double-blind study and the blinding method is as follows: participants will not be aware of the nature of the dose differences and their group; visits will be scheduled in such a way that participants in different groups will not meet each other.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
ethics committee of Iran university of medical sciences
Street address
Vice President for Research and Technology, central Headquarters Building, Iran University of Medical Sciences, next to Milad Tower, Hemmat Highway, Tehran
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Postal code
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Approval date
2025-12-14, 1404/09/23
Ethics committee reference number
IR.IUMS.REHAB.REC.1404.019

Health conditions studied

1

Description of health condition studied
Swallowing disorder following stroke in the acute phase
ICD-10 code
I69.321
ICD-10 code description
Dysphasia following cerebral infarction

Primary outcomes

1

Description

Change in total The Mann Assessment of Swallowing Ability score at 4 time points (before treatment, week 3, week 6, week 12, or follow-up phase).

Timepoint

Before starting treatment, 21, 42 and 84 days after starting treatment

Method of measurement

The Mann Assessment of Swallowing Ability Test: This test consists of 24 items that assess three main areas (oral motor-functional swallowing mechanism-nutritional recommendations and determining the severity of risk in swallowing certain foods). This examination is a clinical assessment and requires few tools for the examination, and these tools include a flashlight, gloves, a suction tube, and some food in different concentrations and water. It is necessary for the examiner to have access to the patient's medical record. The scoring of the test is quantitative and the patient receives a score between 0 and 200. This test has a sensitivity of 73% and a specificity of 89%.

Secondary outcomes

1

Description

Median score of the penetration-aspiration scale with fiberoptic endoscopic evaluation of swallowing (FEES)

Timepoint

Before the start of the intervention, 21, 42 and 84 days after the start of treatment

Method of measurement

A standard 8-point scale is used to grade the occurrence of aspiration or penetration based on the depth of food entry into the airway. A score of one means no food entry into the airway and a score of eight means aspiration without any attempt to expel the food, and is scored using images taken with a fiberoptic endoscopic evaluation of swallowing. In a clinical or research setting, when performing a FEZ test, a speech therapist or specialist will score the severity of the intrusion or aspiration based on the highest level seen during swallowing for each type of food or liquid, using video. This score is a numerical score from 1 to 8, with each number representing a specific condition, from "no intrusion" to "aspiration without effort to clear."

2

Description

Frequency of aspiration severity

Timepoint

Before the start of the intervention, 21, 42 and 84 days after the start of treatment

Method of measurement

The severity of food passing through the true vocal folds and entering the trachea, which can be with or without symptoms, is determined based on the total score of the Massa test. People with scores between 149 and 169 are classified as having mild aspiration. People with scores less than 148 are classified as having moderate aspiration, and people with scores less than or equal to 140 have aspiration disorders.

3

Description

Severity of pharyngeal residue in the vallecula and pyriform sinuses with a 5-point scale protocol for assessing food residue in the vallecula and pyriform sinuses (Yale scale)

Timepoint

Before the start of the intervention, 21, 42 and 84 days after the start of treatment

Method of measurement

In this study, the Yale Residue Protocol will be used as an operational scale for assessing food residue. During flexible endoscopic swallowing assessment, the remaining food morsel after swallowing in the two areas of the volvulus and piriform sinuses will be examined by a trained researcher and scored based on the 5-point Yale scale.

4

Description

Severity of swallowing disorder

Timepoint

Before the start of the intervention, 21, 42 and 84 days after the start of treatment

Method of measurement

The severity of the inability to swallow liquids and foods is calculated as a rank based on the total score of the MASA test. Based on the cut-off score of the test, people with scores between 168 and 177 are classified as having mild dysphagia. People with scores between 139 and 167 are classified as having moderate dysphagia, and people with a score of less than or equal to 138 have severe dysphagia.

Intervention groups

1

Description

Intervention group: The first group received resistance and tongue stretching exercises, high-pressure swallowing, and supraglottic swallowing maneuvers at 25% less than the dose recommended in the literature, and received thermal-sensory stimulation at a fixed dose.

Category

Rehabilitation

2

Description

Intervention group: The second group received resistance and stretching exercises for the tongue, high-pressure swallowing, and supraglottic swallowing

maneuvers at the doses recommended in the literature, and received thermal-sensory stimulation at a fixed dose.

Category

Rehabilitation

3

Description

Intervention group: The third group received resistance and tongue stretching exercises, high-pressure swallowing, and supraglottic swallowing maneuvers 25% more than the dose recommended in the literature, and received thermal-sensory stimulation at a fixed dose.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Rasool Akram Hospital

Full name of responsible person

Mahsa Mehdizadeh behtashi

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2

Recruitment center

Name of recruitment center

Imam Reza Educational, Medical and Research Center

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

Dr. Majid Safa

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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

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Mahsa Mehdizadeh Behtash

Position

PhD candidate

Latest degree

Master

Other areas of specialty/work

Speech therapy

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Person responsible for scientific inquiries

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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
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
Releasable information about participants includes information related to primary and secondary outcomes and some non-identifiable medical information.

When the data will become available and for how long
Access will begin approximately 6 months after results are published.

To whom data/document is available
The data will be accessible to researchers working in academic and scientific institutions.

Under which criteria data/document could be used
A decision will be made after data collection.

From where data/document is obtainable
They can send a message to the relevant researcher's email and request mahsamehdizadeh.slp@gmail.com lghelichi@gmail.com

What processes are involved for a request to access data/document
If other researchers request access to the data, the information will only be provided after the request has been reviewed and approved by the researcher responsible for the project. The applicant will be required to provide a relevant research plan and a written undertaking to maintain the confidentiality of the data and use the information solely within the framework of scientific purposes. The data will be provided to the researchers in an anonymous and coded form, and no patient identification information will be provided.

Comments