

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of Compressed Tongue Range of Motion Exercises on Dysphagia Following Cerebrovascular Accident

Protocol summary

Study aim

Effect of compressed tongue range of motion exercises on dysphagia following cerebrovascular accident

Design

A randomized, blinded, sham controlled clinical trial with a parallel group design of 24 patients

Settings and conduct

24 patients will be divided into two control and experimental groups and Both groups will receive traditional dysphagia treatment for 6 weeks (3 sessions per week). The control group, they will receive the range of motion exercises of the tongue extracted from the traditional dysphagia treatment in the form of a set of 10 exercises in each session while, The experimental group receives the same exercises in each session in a set of 20 exercises (twice as much as the control group). Before starting treatment, after the end of the third week of treatment and after the end of six weeks of treatment, evaluation is done.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. No history of any disease associated with dysphagia such as Parkinson's disease, cervical spinal cord injury, TBI, myasthenia gravis, and amyotrophic lateral sclerosis in the patient's medical history 2. The patient does not have cognitive disorders such as dementia 3. Suffering from dysphagia based on water test 4. Suffering from dysphagia in the oral and oral preparation phase 5. The patient has not yet undergone any treatment program to improve swallowing 6. The patient should be at least 20 years old 7. At least 3 months have passed since the stroke
Exclusion criteria: 1. pregnancy 2. Dysphagia due to drug poisoning 3. Brain stem strokes 4. abandoning the treatment process by the patient 5. The patient's unwillingness to continue the treatment process

Intervention groups

Control group Experimental group

Main outcome variables

Subcategories of Mann assessment of swallowing ability

that contains: Alertness; Cooperation; Auditory comprehension; Dyspraxia; Dysphasia; Dysarthria and etc

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231124060156N1**

Registration date: **2023-12-08, 1402/09/17**

Registration timing: **registered_while_recruiting**

Last update: **2023-12-08, 1402/09/17**

Update count: **0**

Registration date

2023-12-08, 1402/09/17

Registrant information

Name

Farshad Ghalandari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

farshadgh173@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-26, 1402/09/05

Expected recruitment end date

2024-07-25, 1403/05/04

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Effect of Compressed Tongue Range of Motion Exercises on Dysphagia Following Cerebrovascular Accident

Public title
Effect of Compressed Tongue Range of Motion Exercises on Dysphagia Following Cerebrovascular Accident

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Absence of any disease with dysphagia such as Parkinson, Cervical Spinal Cord injury, Traumatic brain injury, Myasthenia gravis and Amyotrophic Lateral Sclerosis Absence of cognitive disorders such as Dementia Dysphagia according to Water Test Dysphagia in oral and preparatory oral phase The patient does not undergone dysphagia treatment The patient must be at least twenty years old At least three month have passed since the stroke
Exclusion criteria:
pregnancy Dysphagia due to drug poisoning Brain stem strokes Abandoning the treatment process by the patient The patient's unwillingness to continue the treatment process

Age
From **20 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **24**

Randomization (investigator's opinion)
Randomized

Randomization description
Stratified randomization is used for this study. In this type of randomization, the number of 24 sample individuals based on the severity of the disease, they are placed in three classes (severe, moderate, mild). Then randomization in each floor by Swap block randomization method is done with block size 2. It is important to mention that the number of people in each floor must be pair numbers. Intervention and control groups called A or B It is assigned that this work is done by a person outside the research team and without the knowledge of the research team. Then randomization is done in each floor like this patient couple (2 patients) has been selected and Using a binary block previously prepared by a person outside the research team (the person doing the concealment) one is assigned to group A and the other to group B. This work continues until the end of patients on each floor. This process is done in all three floors

Blinding (investigator's opinion)

Double blinded

Blinding description
Patients and researcher blinding

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Shahid Fakuri Boulevard, between Shahid Javan Square and Shahid Al Shahidi Square, Danesh Salamat Township, Mashhad University of Medical Sciences

City

Mashhad

Province

Razavi Khorasan

Postal code

99191 91778

Approval date

2023-08-18, 1402/05/27

Ethics committee reference number

IR.MUMS.REC.1402.171

Health conditions studied

1

Description of health condition studied

Dysphagia

ICD-10 code

R13.1

ICD-10 code description

Dysphagia

Primary outcomes

1

Description

1. Dysphagia score in the Mann Assessment of Swallowing Ability 2. Aspiration score in the Mann Assessment of Swallowing Ability test

Timepoint

Before the treatment. At the end of week 3 of treatment. At the end of week 6 of treatment. 6 weeks after the end of the treatment.

Method of measurement

The Mann Assessment of Swallowing Ability

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 12 patients with dysphagia due to stroke who will receive traditional dysphagia treatment exercises for a period of 6 weeks (3 sessions per week). This group will receive the range of motion exercises of the tongue extracted from the traditional treatment of dysphagia in each session as a set of 20 exercises (twice as much as the control group).

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem Hospital

Full name of responsible person

Doctor Gholam Ali Mamori

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Ahmadabad Blvd

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Web page address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Research assistant of Mashhad University of Medical Sciences

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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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Hamideh Ghaemi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Speech therapy

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Other areas of specialty/work

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Position

Master of Science Student

Latest degree

Bachelor

Other areas of specialty/work

Speech therapy

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Mashhad

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