Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

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Iran (Islamic Republic of)

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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

۹۹۱۹۱ ۹۱۷۷۸

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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
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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
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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