

# 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

+98 51 1111 1111

##### 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

#### Street address

Ahmadabad Blvd

#### City

Mashhad

#### Province

Razavi Khorasan

#### Postal code

99199-91766

#### Phone

+98 51 3840 0001

#### Fax

+98 51 3845 3239

#### Email

b.ghaem@mums.ac.ir

#### Web page address

<https://quaem.mums.ac.ir/>

## 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

#### Street address

Fakouri Blvd

#### City

Mashhad

#### Province

Razavi Khorasan

#### Postal code

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#### Phone

+98 51 3879 5031

#### Email

p.relations@mums.ac.ir

### 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

#### Street address

Vakilabad Blvd

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## Person responsible for scientific 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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**Person responsible for updating data****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Farshad Ghalandari

**Position**

Master of Science Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Speech therapy

**Street address**

No. 36, North Khayyam Ave., Bist Metri Zargaran., No  
38 Pelak

**City**

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