

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

### Evaluation of the Effectiveness of Using kinesiology Taping in the Treatment of Oropharyngeal Dysphagia in Stroke Patients Hospitalized in a Rehabilitation Unit

#### Protocol summary

##### Study aim

Determining the effectiveness of Kinesio tape in the treatment of oropharyngeal dysphagia in stroke patients

##### Design

A randomized, controlled, double-blind, parallel-group clinical trial on 44 patients. Randomization will be done with the method of random block permutations.

##### Settings and conduct

44 patients who are selected among the patients hospitalized in the stroke rehabilitation department of Golestan Ahvaz Hospital by the available sampling method, will be placed in two experimental and control groups completely randomly and by random block permutations. The patients of both groups will be treated for 9 days, twice a day. Before and after the treatment they will be evaluated through the Farsi version of the Northwestern Dysphagia Checklist and Flexible Endoscopic Evaluation of Swallowing (penetration-aspiration scale).

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: the occurrence of stroke, the presence of oropharyngeal dysphagia, the ability to perform voluntary swallowing, the Essential level of alertness and cognitive ability, and the score of the Persian version of the Mini-mental state examination above 22. Exclusion criteria I: Impairment in the Esophageal phase of swallowing, history of neurological diseases, history of neuromuscular diseases in the head and neck region, tracheostomy, and any specific skin disease or wound in the anterior neck area.

##### Intervention groups

The interventional group receives traditional treatments and kinesiology tape simultaneously, and the control group receives only traditional treatments.

##### Main outcome variables

The score of the Penetration-Aspiration Scale; The score of Oral phase impairment, Pharyngeal phase impairment,

Pharyngeal phase delay, and Aspiration.

#### General information

##### Reason for update

Given that this research was conducted as part of a student thesis, its implementation was subject to time constraints. Additionally, the study was carried out in a ward with limited capacity (five beds) and stringent inclusion criteria, which further complicated the recruitment process. The criteria for patient inclusion in the study were numerous and restrictive, making it challenging to achieve the initial sample size within the available timeframe. Consequently, the research team, in consultation with a statistical consultant, decided to proceed with a smaller sample size and to conduct the study as a pilot trial. Also, in the methods section, the research team concluded that traditional treatment methods should be tailored specifically to each patient, based on existing studies, to enhance treatment effectiveness. The primary outcome measures were renamed to enhance clarity and ensure they more accurately reflected the variables being assessed. The MMSE score was removed from the inclusion criteria to facilitate the inclusion process. Finally, since the sampling has concluded, the start and end dates of the sampling need to be updated.

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230730058973N1**  
Registration date: **2023-10-09, 1402/07/17**  
Registration timing: **prospective**

Last update: **2025-06-01, 1404/03/11**

Update count: **1**

##### Registration date

2023-10-09, 1402/07/17

##### Registrant information

**Name**  
Fatemeh Saadat

**Name of organization / entity**

**Country**  
Iran (Islamic Republic of)

**Phone**  
+98 61 5325 3123

**Email address**  
saadat.fa@ajums.ac.ir

**Recruitment status**  
**Recruitment complete**

**Funding source**

**Expected recruitment start date**  
2023-09-23, 1402/07/01

**Expected recruitment end date**  
2024-06-21, 1403/04/01

**Actual recruitment start date**  
2024-05-21, 1403/03/01

**Actual recruitment end date**  
2025-01-20, 1403/11/01

**Trial completion date**  
2025-01-20, 1403/11/01

**Scientific title**  
Evaluation of the Effectiveness of Using kinesiology Taping in the Treatment of Oropharyngeal Dysphagia in Stroke Patients Hospitalized in a Rehabilitation Unit

**Public title**  
Effect of kinesiology Taping in treatment of Oropharyngeal Dysphagia

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
The occurrence of stroke in these patients should have been confirmed by a neurologist More than 2 weeks should have passed since their stroke onset An experienced speech and language pathologist should have confirmed the presence of oral-pharyngeal dysphagia in these patients by flexible endoscopic evaluating of swallowing Dysphagia should be caused due to a stroke and should not be caused by surgery or drug toxicity Patients should be able to perform voluntary swallowing in these patients and should not be fed through nasogastric tubes Patients should have the essential level of alertness and cognitive ability to follow orders and implement treatment techniques.  
**Exclusion criteria:**  
Impairment in the Esophageal phase of swallowing History of neurological diseases History of neuromuscular diseases in the head and neck region of the patients Tracheostomy Any specific skin disease or wound in the anterior neck region

**Age**  
From **18 years** old to **70 years** old

**Gender**  
Both

**Phase**  
N/A

## Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

## Sample size

Target sample size: **20**

Actual sample size reached: **20**

## Randomization (investigator's opinion)

Randomized

## Randomization description

The patients included in the study will be placed in two experimental and control groups completely randomly and by random block permutations. The www.sealedenvelope.com website will be used to create random blocks for assigning people to groups. First, a sequence of four blocks will be made. Considering that we have two groups in this study, our blocks of four can be as follows: AABB, ABAB, BABA, BBAA, BAAB, ABBA In these blocks, the letters A and B represent our groups. Then, these six blocks will be numbered and samples will be taken from these six blocks in the form of placement. These blocks will then be put together to form our randomization sequence.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

This study is designed in a manner where the participants, outcome assessors, and data analysts will not know which group each participant is assigned to. As a result, this study is considered to be double-blinded. The participants will be informed of the treatment they will receive, but will not be aware of the treatment given to the other group. They also will not know whether they are in the experimental or control group. Outcome assessors will be unaware of which group, the patient they are assessing belongs to. Also, the data given to the analysts will be named with codes and numbers so that the analysts will not know which data belongs to which group

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Ahvaz Jundishapur University of Medical Sciences

##### Street address

13th Floor, Block A, Central Headquarters of the Ministry of Health, Treatment and Medical Education, Between South Flamak and Zarafshan, Simai Iran St.,

Qods (west), Twon.

**City**

Tehran

**Province**

Tehran

**Postal code**

6135715794

**Approval date**

2023-08-12, 1402/05/21

**Ethics committee reference number**

IR.AJUMS.REC.1402.285

## Health conditions studied

### 1

**Description of health condition studied**

Oropharyngeal Dysphagia

**ICD-10 code**

R13.12

**ICD-10 code description**

Dysphagia, oropharyngeal phase

## Primary outcomes

### 1

**Description**

The score of Penetration-Aspiration Scale

**Timepoint**

At the beginning of the study (before the start of the intervention) and at the end of the 18th treatment session

**Method of measurement**

Flexible Endoscopic Evaluation of Swallowing

### 2

**Description**

The score of Oral phase impairment

**Timepoint**

At the beginning of the study (before the start of the intervention) and at the end of the 18th treatment session

**Method of measurement**

Northwestern Dysphagia Patient Check Sheet

### 3

**Description**

The score of Pharyngeal phase impairment

**Timepoint**

At the beginning of the study (before the start of the intervention) and at the end of the 18th treatment session

**Method of measurement**

Northwestern Dysphagia Patient Check Sheet

### 4

**Description**

The score of Pharyngeal phase delay

### **Timepoint**

At the beginning of the study (before the start of the intervention) and at the end of the 18th treatment session

**Method of measurement**

Northwestern Dysphagia Patient Check Sheet

### 5

**Description**

The score of Aspiration

**Timepoint**

At the beginning of the study (before the start of the intervention) and at the end of the 18th treatment session

**Method of measurement**

Northwestern Dysphagia Patient Check Sheet

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**

Intervention group: This group will receive traditional treatment techniques and kinesiology tape (Sportex, Korea) simultaneously. The treatment will be presented to the patients during 18 treatment sessions ( 9 days and 2 sessions per day). For treatment with kinesiology tape, after cleaning the skin of the anterior neck area completely, an I-shaped tip will first be pulled down from the notch of the thyroid cartilage and attached to the sternum. Then, another V-shaped strip will be connected from the trunk of the hyoid bone to the upper surface of the inner part of the clavicle with downward tension. Then, a transverse tip is placed on the entire hyolaryngeal complex for further restriction. The approximate tension of the tapes used will be 70%. Traditional therapeutic exercises will be performed on the patients after taping, and the tapes will be attached every day before the start of the first daily session and removed after the end of the second treatment session.

**Category**

Rehabilitation

### 2

**Description**

Control group: Patients in this group will only receive traditional treatment for oropharyngeal dysphagia. The traditional treatment used in this study will be determined by a specialist speech-language pathologist based on the results of each patient's clinical assessment. A specific treatment plan will be designed for each patient, including oral sensory stimulation, oral motor exercises (strength, resistance, and range of motion exercises for the lips, jaw, and tongue), swallowing maneuvers (shaker exercise, Mendelssohn maneuvers, labored swallowing, etc.), and compensatory strategies (postural changes, awareness of food

consistency, viscosity, and temperature).

**Category**

Rehabilitation

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Golestan hospital

**Full name of responsible person**

Majid Soltani

**Street address**

Golestan Educational and Specialized and  
Subspecialty Medical Center, Farvardin Ave, Golestan  
Highway, Ahvaz.

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

6135733133

**Phone**

+98 61 3320 4501

**Email**

golestanjpspital@yahoo.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Peyman Zamani

**Street address**

Research Deputy, School of Rehabilitation Sciences,  
Ahvaz Jundishapur University of Medical Science,  
Golestan Highway, Ahvaz.

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

6135733133

**Phone**

+98 61 3374 3108

**Email**

Ahvaz-rehab@ajums.ac.ir

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Ahvaz 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**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Majid Soltani

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Speech therapy

**Street address**

Department of Speech Therapy, School of  
Rehabilitation Sciences, Ahvaz Jundishapur University  
of Medical Science, Golestan Highway, Ahvaz

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

6135733133

**Phone**

+98 61 3374 3101

**Email**

soltani-m@ajums.ac.ir

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Majid Soltani

**Position**

Associate Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Speech therapy

**Street address**

Department of Speech Therapy, School of  
Rehabilitation Sciences, Ahvaz Jundishapur University  
of Medical Science, Golestan Highway, Ahvaz.

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

6135733133

**Phone**

+98 61 3374 3101

**Email**  
soltani-m@ajums.ac.ir

+98 61 3374 3101

**Email**  
soltani-m@ajums.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Majid Soltani

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Speech therapy

**Street address**

Department of Speech Therapy, School of rehabilitation sciences, Ahvaz Jundishapur University of Medical Science, Golestan Highway, Ahvaz.

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

6135733133

**Phone**

## 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