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 l: 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

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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 sgould 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.,

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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 types 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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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
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

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Speech therapy

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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