Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of combined thermal and neuromuscular stimulations on stroke related dysphagic patients

Protocol summary

Study aim
Determine the effect of combined thermal and neuromuscular stimulations on improving oral movements and swallowing disorders in patients with stroke

Design
Clinical trial with control group, with parallel group, double-blind, randomized, on 12 patients. Random allocation software was used for randomization.

Settings and conduct
This study is performed in two hospitals of Namazi and Faghihi in Shiraz. A series of thermal and neuromuscular stimulations that include 10 different stimulations are performed on the mouth, face and neck of a stroke patient with swallowing disorder.

Participants/Inclusion and exclusion criteria
Patients were included in the sample if they were in the acute phase of the stroke (the first 30 days after the stroke); were over 18 years of age and younger than 90 years; and suffered from stroke-related dysphagia (in the oral and pharyngeal phases). In addition, patients had to have a normal level of consciousness. They were excluded if they were unwilling to participate in this study (non-cooperation or non-attendance) or could not collaborate in the swallowing examination because of low consciousness and low comprehension. Another criteria for exclusion from this study was the recurrence of stroke or incidence of other neurological disorders that affect dysphagia.

Intervention groups
The control group received only routine hospital treatments include medical treatments to manage stroke, without any counseling and speech therapy to treat swallowing disorders. But, the treatment group also received protocol-related exercises in addition to routine medical treatments.

Main outcome variables
Mann Assessment Swallowing Ability(MASA) , Motility function test

General information

Reason for update
Finishing data gathering

Acronym

IRCT registration information
IRCT registration number: **IRCT20190618043938N1**
Registration date: **2021-02-11, 1399/11/23**
Registration timing: **prospective**

Last update: **2021-05-18, 1400/02/28**
Update count: **1**

Registration date
2021-02-11, 1399/11/23

Registrant information

Name
Shiva Ebrahimian

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
2021-02-18, 1399/11/30

Expected recruitment end date
2021-03-04, 1399/12/14

Actual recruitment start date
2021-02-18, 1399/11/30

Actual recruitment end date
2021-03-10, 1399/12/20

Trial completion date
2021-04-19, 1400/01/30

Scientific title
The effect of combined thermal and neuromuscular stimulations on stroke related dysphagic patients

Public title
Effect of combined thermal and neuromuscular stimulations on dysphagia

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Patients were included in the sample if they were in the acute phase of the stroke (the first 30 days after the stroke) Patients were over 18 years of age and younger than 90 years Patients suffered from stroke-related dysphagia (in the oral and pharyngeal phases) Patients had to have a normal level of consciousness

Exclusion criteria:
The patients were unwilling to participate in this study (non-cooperation or non-attendance) The patients could not collaborate in the swallowing examination because of low consciousness and low comprehension The recurrence of stroke Incidence of other neurological disorders that affect dysphagia

Age
From **18 years** old to **90 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **12**
Actual sample size reached: **12**

Randomization (investigator's opinion)
Randomized

Randomization description
The subjects of this study were found by using simple random sampling. Randomization sequence was created using “random allocation” software (version 2.0) and stratified in the center, with one to one allocation using random block size of 2 by a nonclinical involvement. The blinded statistician used this software to create a “random number table”; in this table, the order of the blocks is determined. According to that, participants were randomly categorized into two groups: intervention group and control group.

Blinding (investigator's opinion)
Double blinded

Blinding description
A nurse enrolled participants and assigned them to groups; interviewed the patients’ family in order to obtain written informed consent, if the eligibility criteria were met. After assignment to interventions, an examiner who was unaware of the assignments measured the outcomes, the investigator who was unaware of the assignments implemented the protocol and the results were analyzed by another investigator, who was again unaware of the assignments and interventions.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Shiraz University of Medical Sciences

Street address
rehabilitation school of shiraz university of medical science. No.1 Abiverdi St. Chamran Blvd

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Shiraz

Province
Fars

Postal code
7194733669

Approval date
2019-03-11, 1397/12/20

Ethics committee reference number
IR.SUMS.REHAB.REC.1398.006

Health conditions studied

1

Description of health condition studied
Stroke

ICD-10 code
8B20

ICD-10 code description
Fulfills criteria for stroke in that acute symptoms of focal brain injury that have lasted 24 hours or more (or led to death before 24 hours), but subtype of stroke (ischemic or haemorrhagic) has not been determined by neuroimaging or other techniques.

2

Description of health condition studied
Dysphagia

ICD-10 code
MD93

ICD-10 code description
Difficulty in swallowing which may result from neuromuscular disorder or mechanical obstruction. Dysphagia is classified into two distinct types: oropharyngeal dysphagia due to malfunction of the

pharynx and upper oesophageal sphincter; and oesophageal dy

Primary outcomes

1

Description

Swallowing Disorder

Timepoint

Swallowing disorder is measured by Mann assessment swallowing ability (MASA) test at the beginning of the study (before the start of the study) and 7, 14, 21, 28 and 35 days after the intervention.

Method of measurement

Mann assessment swallowing ability (MASA) test

Secondary outcomes

1

Description

Oral Movements

Timepoint

Oral movements are measured by the Motility function test at the beginning of the study (before the start of the study) and 7, 14, 21, 28 and 35 days after the intervention.

Method of measurement

Motility function test

Intervention groups

1

Description

Intervention group: This treatment protocol consists of 10 different stimulations in different areas and are performed without the use of medical gloves. These stimulations are prioritized as they are mentioned in the following: 1. Thermal stimulation of face area: This stimulation is done by using a bag of hot water which is placed on half of the face for 15 seconds. This procedure is similarly performed on the other side and repeated for 5 cycles. 2. Superficial stroking to the face: The therapist’s palm is placed on the half of face and moved down from the hairline (reaching mandible bone) for 1 minute. This procedure is similarly performed on the other side and repeated for 3 cycles. 3. Thermal stimulation of the neck area: This stimulation is done using a bag of hot water which is placed on half of the neck. The bag covered the area from the mandible bone to the clavicle bone for 15 seconds. This procedure was similarly performed on the other side of the neck and repeated for 5 cycles. During 15 seconds of stimulation, we made sure that the water temperature does not lead to rubefaction. 4. Superficial stroking to the neck: The therapist’s palm is placed on half of the neck and moved from mandible bone to clavicle bone for 1 minute. This procedure is similarly performed on the other side of the neck and repeated for 3 cycles.5. Tapping on the suprahyoid triangle of the neck: The neck is tapped gently with 4 fingertips for 1 minute. There is a 30-second break between each set, and the procedure is repeated for 3 cycles. 6. Deep stroking in anterior belly of digastric muscle: The index finger pad is kept in contact at the origin of anterior belly of digastric muscle and is moved along with the muscle fiber (reaching sternocleidomastoid muscle) in each side of the neck for 30 seconds. The same procedure is performed on the other side of the neck and repeated for 3 cycles.7. Superficial stroking to the lips: The therapist’s index finger pad is placed at the corner of the upper lip perpendicularly and moved from left to right for 30 seconds. The same procedure is performed for the lower lip and repeated for 3 cycles. 8. Tapping on lips area: The therapist’s index finger pad is placed at the corner of the upper lip perpendicularly and is tapped from left to right for 30 seconds. The same procedure is performed for the lower lip and repeated for 3 cycles. 9. Intraoral superficial stroking stimulation: For this procedure, we use a tongue blade to stimulate 6 intraoral surfaces for about 1 minute without touching the surrounding structures: tongue (from back to front before triggering the gag reflex), palate (from back to front considering palatine reflex threshold), cheeks (from the inside out), and vestibule of lips (from left to right) for upper and lower lips.10. FN (facial nerves) stimulation: This treatment consisted of 2 stages: a. FN1: The therapist stroke 5 pathways on the face (above the eyebrows, under the eyes, cheeks, around the lips that include upper lip and lower lip) with a piece of ice for 30 seconds in every direction. The similar procedure is performed on the other side of the face. b. FN2: Deep stroking to the face: The therapist’s index finger pad is placed at the start point of every 5 pathways (above the eyebrows, under the eyes, cheeks, around the lips that include upper lip and lower lip) and moved to the endpoint of both sides of the face simultaneously for 30 seconds. The same procedure is performed on the other pathways.If patients' gag reflex is completely eliminated 3 below stimulations added after above protocol: 1. Stimulate the posterior pharyngeal wall: For this procedure, we used a tongue blade to stimulate gently the posterior pharyngeal wall without touching the surrounding structures. The duration of this stimulate was until the gag reflex response observed.2. Depress root of tongue: For this stimulation, we used a tongue blade to depress gently the root of tongue without touching the surrounding structures. The duration of this stimulate was until the gag reflex response observed.3. Elevate the soft plate: For this procedure, we used a tongue blade to elevate gently the soft plate without touching the surrounding structures, for 30 seconds.

Category

Rehabilitation

2

Description

Control group: This group didn't receive any treatment for swallowing disorders. These people followed the instructions and medications prescribed by the doctor according to the hospital routines.

Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Namazi Hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Shiraz 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
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Full name of responsible person
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Not applicable

Title and more details about the data/document
All data except personal information is provided.

When the data will become available and for how long
The start of the access period is 6 months after the acceptance of the article.

To whom data/document is available
In addition to the lead researcher and project supervisor, access to information may be reviewed by the Ethics Committee upon request.

Under which criteria data/document could be used
Researchers can use the data of these studies if necessary and perform advanced analysis or meta-analysis studies.

From where data/document is obtainable
Dr. Shiva Ebrahimian. Shiraz. Chamran Boulevard. Abivardi St. 1. Faculty of Rehabilitation Sciences. Cel No. : 09133035770 . Email: ebrahimsh@sums.ac.ir

What processes are involved for a request to access data/document
After 6 months of accepting the article, while announcing a written request to the executor of the project to receive information and a clear reason on how to use the information in an official letter to obtain permission from the ethics committee, comment and if approved by the ethics committee with emphasis on confidentiality The requested information is provided to the applicant.

Comments