

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

Evaluation the effect of biofeedback therapy in the treatment of patient with chronic dysphagia due to stroke

Protocol summary

2016-05-23, 1395/03/03

Summary

(1) Objectives: The aim of this study was to determine the effects of biofeedback to improve chronic dysphagia in patients with stroke. (2) Design: This study is a before and after treatment, without placebo control, unicentral and in second phase of clinical trial. (3) Setting and conduct: The study population are patients with dysphagia referring to firoozgar hospital physical medicine and rehabilitation clinic via an advertisement. The sample size is 16 people. (4) Participants including major eligibility criteria: Inclusion criteria are patients with chronic dysphagia due to stroke, exclusion criteria are lack of awareness or inappropriate collaboration. (5) Intervention: The patients treated for 10 sessions of biofeedback. To do biofeedback therapy, device electrodes installed under chin, between the mandible and hyoid and front of the neck. Then, patient is asked to do Mendelsohn maneuver. Before the first meeting, the fifth and tenth, the patient ability to swallow food and water, is under review and will be recorded on the chart. Patients will be followed one month after completion of treatment. (6) Main outcome measures (variables): The main outcome of the study are Functional Outcome Intake Scale (FOIS) mean score and sub-mental muscle contractions which will be measured before treatment, immediately and one month after the end of sessions.

Registrant information

Name

Tannaz Ahadi

Name of organization / entity

Iran University of Medical Science

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Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences

Expected recruitment start date

2015-06-22, 1394/04/01

Expected recruitment end date

2016-03-16, 1394/12/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of biofeedback therapy in the treatment of patient with chronic dysphagia due to stroke

Public title

The efficacy of exercise therapy in the treatment of chronic swallowing disorder in stroke patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : Patients with chronic dysphagia due to

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016010324621N3**

Registration date: **2016-05-23, 1395/03/03**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

stroke Exclusion criteria :Unconsciousness; Failure to obey orders

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 16

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Iran University of Medical Science

Street address

Medical faculty, Iran University of Medical Science,
Hemmat High way

City

Tehran

Postal code

Approval date

2015-05-30, 1394/03/09

Ethics committee reference number

94/1309/105/س.IR.IUMS.REC

Health conditions studied

1

Description of health condition studied

Swallowing disorder

ICD-10 code

R13.1

ICD-10 code description

Dysphagia

Primary outcomes

1

Description

Score obtaining from FOIS Questioner

Timepoint

Before,after last session and 1 month after intervention

Method of measurement

FOIS Questioner

2

Description

Submental muscles contraction amplitude

Timepoint

Before,fifth ,after last session and 1 month after intervention

Method of measurement

Biofeedback device

Secondary outcomes

1

Description

Age

Timepoint

Before the intervention

Method of measurement

Question

2

Description

Sex

Timepoint

Before the intervention

Method of measurement

Question

3

Description

Dysphagia duration

Timepoint

Before the intervention

Method of measurement

Question

4

Description

Type of stroke

Timepoint

Before the intervention

Method of measurement

Medical records

Intervention groups

1

Description

Mendelssohn trainings, in which the hand is placed on

the front of neck and patient is ordered to swallow, and biofeedback therapy executed at the same time , for 20 minutes in 10 sessions. A month later , the patient swallowing function will be assessed.

Category

Rehabilitation

Recruitment centers**1****Recruitment center****Name of recruitment center**

Firoozgar Educational Hospital

Full name of responsible person

Seyyed Mohammad Moeini Taba Zavareh

Street address

Firoozgar hospital, Physical medicine and rehabilitation clinic, Behafarin St, Valiasr square, Tehran

City

Tehran

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice chancellor for research, Iran University of Medical Sciences

Full name of responsible person

Pejman Madani

Street address

Iran University of Medical Sciences, Hemmat high way

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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

Vice chancellor for research, Iran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Seyyed Mohammad Moeini Taba Zavareh

Position

Physiatry Resident

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Position

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Other areas of specialty/work**Street address**

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty