Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The Effect of Traditional Dysphagia Therapy on The Swallowing function in patients with Multiple Sclerosis

Protocol summary

Summary

Dysphagia is one of the most common disorders associated with multiple sclerosis, which, if untreated, it can have a major impact on quality of life and dysphagia leads to weight loss, aspiration and lung infections.1- The purpose of this research is to study the effect of traditional dysphagia therapy on swallowing function for MS patients with dysphagia. 2- This study is a randomized double-blind clinical trial. 3- 20 patients with multiple sclerosis who Sinai Hospital Research Center, Tehran University of Medical Sciences were admitted with complaints of dysphagia, after considering the inclusion and exclusion criteria were enrolled in the study. Patients were randomly allocate into two groups. The principal researcher is therapist and will aware of types of treatment but she will blind to outcomes of assessment that done by assessor.On the other hand all patients and assessor blinded to types of treatment.It should be noted that patients were randomly allocated into two groups by the secretary of dysphagia clinic and so, therapist and assessor do not involve in allocating patients. 4- Inclusion criteria: Multiple Sclerosis patient; age ranges 20-60; Not receiving steroid drugs in the last month; Not having history of diseases associated with dysphagia; Not having history of cognitive disorders; dysphagia diagnosed by MASA test; Not having history of receiving any dysphagia therapy; Exclusion criteria: Having Severe reflux; Having dysphagia due to drug toxicity; Pregnancy; The patient's unwillingness to continue treatment. 5- Treatment:treatment protocol of the first group including compensatory postural changes, swallowing maneuvers, oral motor exercises and usual care. This treatment continued for 30 minutes, three days a week for 6 consecutive weeks will be provided. The second group (control group) will receive usual care, including changes in speed, volume and viscosity of food for 30 minutes, three days a week for 6 consecutive weeks will be provided. The presence and severity of dysphagia and aspiration assessments at baseline, at the end of the third week, the end of the sixth week and the end of the twelfth week (Follow up) is done in all groups. 6- Outcome measures: The score of MASA test and the score of aspiration-penetration scale

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016022426721N2**
Registration date: **2016-07-20, 1395/04/30**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-07-20, 1395/04/30

Registrant information

Name

Maryam Tarameshlu

Name of organization / entity

School of Rehabilitation,Tehran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tehran University of Medical Sciences

Expected recruitment start date

2016-06-21, 1395/04/01

Expected recruitment end date

2016-12-21, 1395/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Traditional Dysphagia Therapy on The Swallowing function in patients with Multiple Sclerosis

Public title

Dysphagia therapy in Multiple Sclerosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria 1- Multiple Sclerosis patient; 2- age ranges 20-60; 3- Not having history of relapses and not receiving steroid drugs in the last month; 4- Not having history of stroke, Parkinson's disease, cervical spinal cord injury, traumatic brain injury, amyotrophic lateral sclerosis and myasthenia gravis; 5- Not having history of cognitive disorders such as Dementia; 4- dysphagia and aspiration diagnosed by MASA test; 6-Not having history of receiving any dysphagia therapy; Exclusion criteria: 1- Having Severe reflux; 2- Having Dysphagia due to drug toxicity; 3- Pregnancy; 4- The patient's unwillingness to continue treatment

Age

From **20 years** old to **59 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Sixth floor, Center building of University, Qods street, Keshavarz Blvd

City

Tehran

Postal code

Approval date

2016-05-24, 1395/03/04

Ethics committee reference number

IR.TUMS.VCR.REC.1395.51

Health conditions studied

1

Description of health condition studied

Dysphagia

ICD-10 code

R13

ICD-10 code description

Difficulty in swallowing

Primary outcomes

1

Description

MASA Score

Timepoint

Beginning the first week, End of the third week, End of the sixth week, End of the twelfth week

Method of measurement

standard questionaire

Secondary outcomes

1

Description

Aspiration-Penetration Scale Score

Timepoint

Beginning the first week, End of the third week, End of the sixth week, End of the twelfth week

Method of measurement

Fiberoptic Endoscopic Evaluation of Swallowing

Intervention groups

1

Description

Intervention Group: The first group is provided traditional dysphagia therapy. It is included computational treatments , postural changes, oral-motor exercise, swallowing manures and usual cares. This treatment is provided for 30 min in 3 days of week and for 6 weeks.

Category

Rehabilitation

2

Description
Control Group : The second group is provided usual cares. This protocol included changes in speed, volume and viscosity of food. This treatment is provided for 30 min in 3 days of week and for 6 weeks.

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Multiple Sclorosis Research Center, Sina Hospital

Full name of responsible person
Dr. Amir Reza Azimi

Street address
Sina Hospital, Hassan Abad Squ, Imam khomeini St, Tehran

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Tehran University of Medical Sciences

Full name of responsible person
Dr. Masood Yunesian

Street address
Sixth floor, Center building of University, Qods street, Keshavarz Blvd ,Tehran

City
Tehran

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, Tehran 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
Tehran University of Medical Sciences, School of Rehabilitation

Full name of responsible person
Maryam Tarameshlu

Position
PhD candidate of Speech Therapy

Other areas of specialty/work

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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