

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 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

Country

Iran (Islamic Republic of)

Phone

+98 21 7726 6778

Email address

tarameshlu@razi.tums.ac.ir

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 questionnaire

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 Sclerosis 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

Street address

Piche Shemiran, Enghelab Ave, Tehran, Iran

City

Tehran

Postal code

Phone

+98 21 7753 3939

Fax

Email

m.tarameshlu@gmail.com

Web page address

Person responsible for scientific 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

Street address

Piche Shemiran, Enghelab Ave, Tehran, Iran

City

Tehran

Postal code

Phone

+98 21 7753 3939

Fax

Email

tarameshlu@razi.tums.ac.ir

Web page address

Person responsible for updating data

Contact

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Street address

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Postal code
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Fax
Email
tarameshlu@razi.tums.ac.ir
Web page address

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