Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jul 2026

Comparative Study of effectiveness of Combined treatment of dysphagia(Traditional Dysphagia Therapy &Transcranial Magnetic Stimulation) and other two treatments in Stroke Patients".

Protocol summary

Summary

The aim of this study is comparative study of the process and effects of Traditional Dysphagia Therapy, Transcranial Magnetic Stimulation and Combination of them in Stroke patients with Dysphagia. Design of the study is randomized clinical trial and double blinded. Inclusion Criteria: 1-Subacute Stroke patient with dysphagia 2-Suffering from dysphagia and aspiration diagnosed by MASA 3- No dysphagia therapy. Exclusion Criteria: 1- Dementia and Alzheimer and dysphagia due to other neurogenic Disease 2- Severe Aphasia 3_ Dysphagia due to drug toxicity 4_ Agitation, with decreased level of consciousness, or otherwise noncompliant 15 Stroke patients with dysphagia participate in three groups. The first group are provided traditional dysphagia therapy. This protocol is included computational treatments , postural changes, oromotor exercise and swallowing manures. This treatment is provided for 30 min in 3 days of week and for 6 weeks. This group is control. The second group is provided inhibitory Repetitive Transcranial Magnetic Stimulations in healthy hemisphere. Stimulations were performed at 1 Hz for 20 min at 20% above the threshold value. It was repeated each day for 5 days. The third group is given combined treatment . Firstly patients are given rTMS for 5 day and simultaneously are given TDT for 3days in week for 6 weeks. MASA Test will be performed before, end of fifth session, end of tenth session, end of fourth week and the end of sixth week and determined existence and severity of dysphagia and aspiration in all of the patients in every group.

General information

Acronym

TDT TMS

IRCT registration information

IRCT registration number: **IRCT201202218629N1**
Registration date: **2013-03-27, 1392/01/07**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-03-27, 1392/01/07

Registrant information

Name

Leila Ghelichi

Name of organization / entity

Tehran University Of Medical Sciences, Rehabilitation School

Country

Iran (Islamic Republic of)

Phone

+98 21 2222 8051

Email address

l-ghelichi@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2012-06-21, 1391/04/01

Expected recruitment end date

2013-06-22, 1392/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative Study of effectiveness of Combined treatment of dysphagia(Traditional Dysphagia Therapy &Transcranial Magnetic Stimulation) and other two treatments in Stroke Patients".

Public title
Treatment of Swallowing disorders in stroke patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion Criteria: 1-Subacute(at least one week after the accuring of stroke) Stroke patient with dysphagia 2-Patients' rang of age is between 20-80 3-Patients from Both gender 4-Suffering from dysphagia and aspiration diagnosed by MASA(Mann Assessment of Swallowing Ability) 5- they have not received any Dysphagia therapy. Exclusion Criteria: 1- Dementia and Alzheimer and dysphagia due to other neurogenic Disease 2_ Significant reflux 3- Severe Aphasia 4_ Dysphagia due to drug toxicity 5- severe Reflux 6_ Agitation, with decreased level of consciousness, or otherwise noncompliant 7_ Pregnancy
Age
From **20 years** old to **80 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **15**
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
Tehran University of Medical Sciences
Street address
Sixth floor, Center building of University, Qods street, Keshavarz Blvd
City
Tehran
Postal code
Approval date
2012-12-26, 1391/10/06
Ethics committee reference number
130/2435/د

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
Score of MASA test
Timepoint
Before treatment,5th session,10th session,the end of forth week of treatment and the end of sixth week of treatment
Method of measurement
MASA test

2

Description
Dysphagia
Timepoint
Before treatment,5th session,10th session,the end of forth week of treatment and the end of sixth week of treatment
Method of measurement
MASA test

3

Description
Severity of Dysphagia
Timepoint
Before treatment,5th session,10th session,the end of forth week of treatment and the end of sixth week of treatment
Method of measurement
MASA test

4

Description
Aspiration
Timepoint
Before treatment,5th session,10th session,the end of forth week of treatment and the end of sixth week of treatment
Method of measurement
MASA test

5

Description
Severity of Aspiration
Timepoint
Before treatment,5th session,10th session,the end of forth week of treatment and the end of sixth week of treatment
Method of measurement
MASA test

Secondary outcomes

empty

Intervention groups

1

Description
Control Group : The first group are provided traditional dysphagia therapy. this protocol is included competional treatments , postural changes, oromotor exercies and swallowind manuers. this treatments is provided in 30 min for 3 days of week and for 6 weeks.
Category
Rehabilitation

2

Description
Intervention Group : The second group are provided inhibitory Repatative Transcranial Magnetic Stimulations (rTMS) in healty hemisphere. Stimulations were performed at 1 Hz for 20 min at 20% above the threshold value. It was repeate each day for 5 days. All stimulations were carried out using a Magstim superrapi stimulator (Magstim, Whitland, Dyfed, UK) equipped with a air-refreshed, double, 70-mm, figure-of-eight coil (peak magnetic field = 2 T), at the maximal output of the stimula. The vertex of the cranium was first identified. The coil was then positioned 2–4 cm anteriorlyand 4–6 cm laterally and moved around in this area to obtain the highest electromyographic mylohyoid response.
Category
Treatment - Devices

3

Description
Intervention Group: The third group is given combined treatment(TDT and rTMS). Firstly patients are given rTMS for 5 day and Simultaneously are given TDT for 3days in week for 6 weeks. In every day that is provided two treatment Simultaneously patients are given rTMS for 20 min and after short rest (5-10 min) another treatment (TDT) is provided for 30 min by speech& language Pathologist
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Firoozgar Hospital
Full name of responsible person
Street address
City
Tehran

2

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr Fotoohi
Street address
Center building of Tehran University of Medical Sciences, Qods Steert, Keshavarz Blve, Tehran
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
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
Full name of responsible person
Leila Ghelichi

Position
PhD students of Speech therapy
Other areas of specialty/work
Street address
Speech therapy Department, Rehabilitation School, Shahnazari Street, Madar Squre, Mirdamad
City
Tehran
Postal code
Phone
+98 21 2222 8051
Fax
Email
l-ghelichi@razi.tums.ac.ir ,lghelichi@gmail.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Leila Ghelichi
Position
PhD student of Speech Therapy
Other areas of specialty/work
Street address
Speech therapy Department, Rehabilitation School, Shahnazari Street, Madar Squre, Mirdamad
City
Tehran
Postal code
Phone
+98 21 2222 8051
Fax
Email
l-ghelichi@razi.tums.ac.ir ,lghelichi@gmail.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Leila Ghelichi
Position
PhD Student of Speech Therapy
Other areas of specialty/work
Street address
Speech therapy Department, Rehabilitation School, Shahnazari Street, Madar Squre, Mirdamad
City
Tehran
Postal code
Phone
+98 21 2222 8051
Fax
Email
l-ghelichi@razi.tums.ac.ir ,lghelichi@gmail.com
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