

# 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".

2012-12-26, 1391/10/06

**Ethics committee reference number**  
130/2435/3

**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**

**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 fourth 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 Squire, Mirdamad

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**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tehran University of Medical Sciences

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**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*