

# 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8871 8207

##### Email address

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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

#### 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

#### 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

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

**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, 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

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

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

Iran University of Medical Sciences

**Full name of responsible person**

Tannaz Ahadi

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Physical Medicine and Rehabilitation Specialist

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**Postal code****Phone**

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**Fax****Email****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*