

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

12 Jul 2026

### Evaluation of the therapeutic effect of pyridostigmine in post-stroke dysphagia

#### Protocol summary

##### Study aim

1. Evaluation of the effect of pyridostigmine on MASA score improvement and PSR time in patients with stroke-induced swallowing disorder
  3. The relationship between age, gender and location of stroke lesion with the effect of pyridostigmine in the recovery of stroke-induced swallowing disorder
- Applied:
1. Early diagnosis of swallowing disorder in stroke patients using appropriate clinical methods
  2. Improving stroke prognosis by preventing complications of dysphagia and aspiration
  3. Reduce public health costs by reducing stroke complications

##### Design

Two arm parallel groups randomized double-blind pilot trial (each group:12 patients)and randomized groups based on blocking

##### Settings and conduct

Sampling: Firoozgar hospital Neurology department and ICU. Patients and also speech therapists who perform basic and fallow up assessments of patients are not aware of belonging to the intervention or control group. Data analysis will be done blinded and based on data encoding.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with ischemic stroke diagnosed based on CT scan or MRI, which are based on MASA score (score>177) and PSR reflex time (time>than 1.5 s), have stroke-related dysphagia within 14 to 180 days of their stroke. (Due to the high probability of spontaneous swallowing recovery in stroke patients in the first two weeks, patients have not entered in the first 14 days). Examination: by the speech therapist at the beginning of the study and follow-up

Exclusion criteria: Age<18 years, hemorrhagic stroke, head and/or neck trauma

##### Intervention groups

Intervention group: The group who receive pyridostigmine tablets three times a day for one month.

Control group: The group receiving placebo tablets with

similar amounts. Both intervention and control groups will benefit from speech therapy similarly during this period.

##### Main outcome variables

MASA score; PSR time

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210216050383N1**

Registration date: **2021-02-21, 1399/12/03**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-02-21, 1399/12/03**

Update count: **0**

##### Registration date

2021-02-21, 1399/12/03

##### Registrant information

##### Name

Seyedeh Enssieh Hashemi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2256 3192

##### Email address

enssieh.hashemi@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-02-18, 1399/11/30

##### Expected recruitment end date

2021-03-20, 1399/12/30

##### Actual recruitment start date

empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
Evaluation of the therapeutic effect of pyridostigmine in post-stroke dysphagia

**Public title**  
Effect of pyridostigmine in post-stroke dysphagia

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
 Patients with ischemic stroke revealed by CT scan or MRI 14 to 180 days before intervention and diagnosed to have post-stroke dysphagia according to MASA score (more than 177) and PSR time (more than 1.5 s) assessed by a speech pathologist.  
**Exclusion criteria:**  
 Younger than 18 Hemorrhagic stroke Stroke onset before 14 days or after 180 days Head and/or neck injuries

**Age**  
From **18 years** old

**Gender**  
Both

**Phase**  
1-2

**Groups that have been masked**

- Participant
- Care provider
- Outcome assessor
- Data analyser

**Sample size**  
Target sample size: **24**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
We use block size 4 randomization with equal probability for eligible patients to enter groups A and B. According to Block Size 4, we have six possible combinations for assigning individuals to groups, including AABB, ABAB, BAAB, BABA, BBAA and ABBA. At the beginning of the study, we randomly select one of these arrangements and four eligible patients are placed on each block, respectively. We repeat this process several times until all eligible patients are examined. Randomization Tool: Random Numbers Table Randomization is concealed in an sealed envelope.

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
Patients who participate in the project based on informed consent do not know their belonging to the intervention or control group. Due to the nature of the intervention and the design method of the study, only the specialist physician in the course of the treatment is aware of the intervention. Other physicians and speech pathologist who perform examinations of the patients at the

beginning and in subsequent referrals will be unaware of the patient's belonging to the intervention or control group. Also, the statistician does not know the identity of the patients and the researcher who collects the patients' information only collects the information through a numerical list in which the patients' names are not available.

**Placebo**  
Used

**Assignment**  
Parallel

**Other design features**  
This study is currently a pilot study.

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**  
**Name of ethics committee**  
 Research Ethics committee of Iran University of Medical Sciences  
**Street address**  
 No.3, plate No. 6, Khodajoo Alley, South Ekhtiarieh Ave, Pasdaran Ave  
**City**  
 Tehran  
**Province**  
 Tehran  
**Postal code**  
 1958646863  
**Approval date**  
 2020-12-26, 1399/10/06  
**Ethics committee reference number**  
 IR.IUMS.REC.1399.1064

## Health conditions studied

### 1

**Description of health condition studied**  
 Dysphagia following cerebral infarction  
**ICD-10 code**  
 I69.391  
**ICD-10 code description**  
 Dysphagia following cerebral infarction

## Primary outcomes

### 1

**Description**  
 Grade of patients dysphagia according to Mann Assessment of Swallowing Ability score sheet  
**Timepoint**  
 Measuring the score of Mann Assessment of Swallowing Ability questionnaire in patients at the beginning of the study (before the intervention) and 30 days after the use

of pyridostigmine  
**Method of measurement**  
Mann Assessment of Swallowing Ability questionnaire

## 2

### **Description**

Pharyngeal swallowing Reflex time

### **Timepoint**

Measurement of pharyngeal swallowing reflex time in patients at the beginning of the study (before the intervention) and 30 days after the use of pyridostigmine

### **Method of measurement**

Assessed by Speech pathologist bedside

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group: Tablet Pyridostigmine 60 mg TDS before each meals for one month

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Control group: a Placebo tablet one before each meal (three times a day) for one month

#### **Category**

Placebo

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Firouzgar Hospital

##### **Full name of responsible person**

Seyedeh Enssieh Hashemi

##### **Street address**

Firouzgar hospital, Behafarin Ave, Hafez Ave, Karimkhan Ave

##### **City**

Tehran

##### **Province**

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##### **Postal code**

1593747118

##### **Phone**

+98 21 2256 3192

##### **Email**

enssieh.hashemi@gmail.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Iran University of Medical Sciences

##### **Full name of responsible person**

Iran University of medical sciences

##### **Street address**

Iran University of Medical Sciences, Hemmat highway

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

##### **Phone**

+98 21 86701

##### **Email**

PR@iums.ac.ir

#### **Grant name**

#### **Grant code / Reference number**

#### **Is the source of funding the same sponsor organization/entity?**

Yes

#### **Title of funding source**

Iran University of Medical Sciences

#### **Proportion provided by this source**

100

#### **Public or private sector**

Public

#### **Domestic or foreign origin**

Domestic

#### **Category of foreign source of funding**

empty

#### **Country of origin**

#### **Type of organization providing the funding**

Academic

## **Person responsible for general inquiries**

#### **Contact**

##### **Name of organization / entity**

Iran University of Medical Sciences

##### **Full name of responsible person**

Seyedeh Enssieh Hashemi

##### **Position**

Resident

##### **Latest degree**

Medical doctor

##### **Other areas of specialty/work**

Neurology

##### **Street address**

No.3, plate No.6, Khodajoo Alley, Ekhtiarieh jonubi Ave, Pasdaran Ave, Tehran, Iran

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Seyedeh Enssieh Hashemi

**Position**

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**Latest degree**

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**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

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**Full name of responsible person**

Seyedeh Enssieh Hashemi

**Position**

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**Latest degree**

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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

Yes - There is a plan to make this available

### Statistical Analysis Plan

Yes - There is a plan to make this available

### Informed Consent Form

Yes - There is a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Yes - There is a plan to make this available

### Data Dictionary

Yes - There is a plan to make this available

### Title and more details about the data/document

Unidentifiable data of individuals and related dictionaries are prepared as checklists that can be provided to other researchers after the study is finished and the results are published. Additional documents such as study protocol, data analysis program, etc. will also be shared. Also, the informed consent form and clinical study report can be shared.

### When the data will become available and for how long

Starting access period after publishing the study results

### To whom data/document is available

After publishing the results of the study, the data and other documents of the study are for researchers, including employed in academic and scientific institutions and people who are engaged in the industry, will be accessible.

### Under which criteria data/document could be used

Due to the lack of the patients' personal data, the use of documentation and analysis on it is permitted.

### From where data/document is obtainable

Applicants can send a message to the trial plan's executor via email enssieh.hashemi@gmail.com or communicate with the executor via correspondence with the postal address of the sampling location.

### What processes are involved for a request to access data/document

The requester of these documents or data files will list their request by email and the request will be processed as soon as possible.

### Comments