Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

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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

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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

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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