

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

Investigating the effect of Pyridostigmine to improving dysphagia in stroke patients

Protocol summary

Study aim

The effect of pyridostigmine in improving dysphagia in patients with stroke

Design

Clinical pilot trial with intervention and control groups (30 patients in each group), with parallel groups, double-blind, randomized based on blocking

Settings and conduct

Study site: All stroke patients admitted to Kowsar Hospital Sanandaj, the patients and the doctor of the plan who performs the baseline and follow-up evaluations of the patients are not aware of whether they belong to the intervention or control group, and the data analysis will be based on data coding without knowing whether they belong to the intervention or control group.

Participants/Inclusion and exclusion criteria

Entry criteria: Patients diagnosed with acute ischemic stroke based on imaging who also have stroke-related dysphagia. Additionally, patients must have a Glasgow Coma Scale score greater than 12. Exclusion criteria: Age under 18, hemorrhagic stroke, head or neck trauma.

Intervention groups

Intervention group: 30 patients with stroke and dysphagia who received 120 mg of pyridostigmine produced by Alborz Daru under the brand Pyramist every 12 hours, were included in the intervention. Control group: 30 patients with stroke and dysphagia who received placebo capsules (corn starch) in addition to their routine medications.

Main outcome variables

1: Evaluation of dysphagia score 2: Evaluation the average score of side effects 3: Evaluation the average score of the volume viscosity swallow test 4: Evaluation the average score of the eating assessment tool 5: Evaluation the average score of the standardized swallowing assessment test 6: Evaluation the average score of the water swallow test

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230520058232N1**

Registration date: **2023-06-26, 1402/04/05**

Registration timing: **prospective**

Last update: **2023-06-26, 1402/04/05**

Update count: **0**

Registration date

2023-06-26, 1402/04/05

Registrant information

Name

Farzaneh Karimian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 87 3361 1231

Email address

fkarimian1363@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-23, 1402/05/01

Expected recruitment end date

2023-08-23, 1402/06/01

Actual recruitment start date

2023-07-23, 1402/05/01

Actual recruitment end date

2023-08-23, 1402/06/01

Trial completion date

2023-09-22, 1402/06/31

Scientific title

Investigating the effect of Pyridostigmine to improving dysphagia in stroke patients

Public title

Effect of pyridostigmine in stroke-related dysphagia

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Confirming the diagnosis of stroke disease based on imaging and laboratory results GCS level of consciousness greater than 12 Age above 18 years old

Exclusion criteria:

Age less than 18 years hemorrhagic stroke head and/or neck trauma

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The method of randomization in this study was based on the block randomization method. Blocking was usually used in order to balance the number of samples assigned to each of the studied groups. This feature helps the researchers to have the same number of samples assigned to each of the studied groups in cases where intermediate analyzes are needed during the sampling process. Blocking was done in two ways. In the first method, the size of all the blocks is equal (for example, in a two-group trial, there are 8 blocks including 4 participants in the intervention group and 4 participants in the control group), and in the second method, the size of the blocks was chosen randomly (for example, blocks of 6, 8, 10 and 14) in which there is an equal number of each group in each block. In this study, the samples are selected using random selection from four randomized blocks. The four randomized blocks selected are AABB, ABAB, ABBA, BBAA, BABA, BAAB (A: patients receiving pyridostigmine and B: patients receiving placebo).

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients who participate in the project based on informed consent do not know whether they belong to the intervention or control group. Due to the nature of the intervention and the method of study design, only the specialist doctor of the plan is aware of the type of treatment. Other doctors who perform examinations and examinations of patients at the beginning and in

subsequent visits, 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 information of the patients collects the information only through a numerical list that does not contain the names of the patients.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Kurdistan University of Medical Sciences

Street address

Kurdistan University of Medical Sciences, across from Shadi Hotel, Pasdaran Street

City

Sanandaj

Province

Kurdistan

Postal code

1344666177

Approval date

2022-06-25, 1401/04/04

Ethics committee reference number

IR.MUK.REC.1401.065

Health conditions studied**1****Description of health condition studied**

Stroke related dysphagia

ICD-10 code

I69.391

ICD-10 code description

Dysphagia following cerebral infarction

Primary outcomes**1****Description**

Severity of patients' dysphagia based on the score of Swallowing Disturbance Questionnaire (SDQ)

Timepoint

Measuring the score of the questionnaire in patients at the beginning of the study and after the start of treatment until 14 days after the end of treatment

Method of measurement

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: receiving pyridostigmine 120 mg every 12 hours for three weeks

Category

Treatment - Drugs

2

Description

Control group: receiving placebo every 12 hours for three weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Kowsar hospital

Full name of responsible person

Farzaneh Karimian

Street address

Kurdistan University of Medical Sciences, across from Shadi Hotel, Pasdaran Street

City

Sanandaj

Province

Kurdistan

Postal code

1344666177

Phone

+98 87 1613 1311

Fax

+98 87 1666 4674

Email

fkarimian1363@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

khaled Rahmani

Street address

Kurdistan University of Medical Sciences, across from Shadi Hotel, Pasdaran Street

City

Sanandaj

Province

Kurdistan

Postal code

1344666177

Phone

+98 87 1613 1311

Fax

+98 87 1666 4674

Email

fkarimian1363@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Sanandaj 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

Sanandaj University of Medical Sciences

Full name of responsible person

Farzaneh Karimian

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Neurology

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Kurdistan University of Medical Sciences, across from Shadi Hotel, Pasdaran Street

City

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Kurdistan

Postal code

1344666177

Phone

+98 87 1613 1311

Email

fkarimian1363@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Sanandaj University of Medical Sciences

fkarimian1363@gmail.com

Full name of responsible person

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Person responsible for updating data

Contact

Name of organization / entity

Sanandaj University of Medical Sciences

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Email

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

Non-identifiable individual data and related dictionaries are prepared in the form of checklists that can be made available to other researchers after the end of the study and publication of its results. In addition, relevant additional documents such as study protocol, data analysis plan, etc. will also be shared. The informed consent form and clinical study report are also shareable.

When the data will become available and for how long

Start of access period after publication of study results

To whom data/document is available

The study data and other documents will be accessible to researchers, including those employed in academic and scientific institutions, individuals working in industry, etc., after publication of the study results

Under which criteria data/document could be used

Given the non-disclosure of patients' personal data, the use of documents and conducting analysis on them is authorized

From where data/document is obtainable

Applicants can request the desired documents or data from the trial's executor by sending a message to fkarimian1363@gmail.com via email or by corresponding with the executor at the sampling location's postal address

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

The requester mentions their request via the email mentioned, and it will be addressed as soon as possible

Comments