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
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Iran (Islamic Republic of)
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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

Swallowing Disturbance Questionnaire

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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Sanandaj University of Medical Sciences
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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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Person responsible for updating data

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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
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