Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Nov 2026

Studying the Effects of Pyridostigmine on Dysphagia in Patients With Multiple Sclerosis: a Randomized Triple-Blind Placebo-Controlled Clinical Trial

Protocol summary

Study aim
Studying the effects of pyridostigmine on dysphagia in patients with multiple sclerosis

Design
Clinical trial with two arms, intervention group with pyridostigmine and control group with placebo, parallel grouping, a total of 48 participants, triple blinded, block randomization with blocks of 4 using software.

Settings and conduct
Patients with multiple sclerosis who are referring to Sina hospital, using convenient sampling. The participants will take either pyridostigmine or placebo for three weeks. The dose of study is 60 mg tablets, three times a day.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: A definite diagnosis of multiple sclerosis is made based on the 2017 McDonald criteria The patient's willingness toward participation and cooperation. A minimum Age of 18 and maximum of 55. A DYMUS score of at least 3 Exclusion Criteria: Other neurological disorders Any comorbidity due to previous neurological disorders The patient is currently pregnant or breastfeeding. A history of relapse (if MS type is relapsing-remitting) in the previous 3 months. An Expanded Disability Status Scale (EDSS) score above 7.5. Dysphagia caused by other disorders than MS. Currently being under treatment with pyridostigmine for any reasons. A history of hypersensitivity to anticholinesterase inhibitors or any of the compounds in our placebo. Having a decision to start any other treatment for dysphagia in time of the study, or having started in the last 3 months. The patient has mechanical obstruction in intestinal or urinary tract.

Intervention groups
Intervention group: pyridostigmine tablet, PO, three times a day for three weeks. Control group: placebo tablet, the same dosing as pyridostigmine group

Main outcome variables
Patient's score in DYMUS, EAT-10 and SWAL-QOL questionnaires

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20090429001859N11**
Registration date: **2023-09-10, 1402/06/19**
Registration timing: **prospective**

Last update: **2023-09-10, 1402/06/19**
Update count: **0**

Registration date
2023-09-10, 1402/06/19

Registrant information

Name
Mohammad Ali Sahraian

Name of organization / entity
Tehran University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 21 6634 8571

Email address
msahrai@sina.tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-09-23, 1402/07/01

Expected recruitment end date
2024-07-21, 1403/04/31

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Studying the Effects of Pyridostigmine on Dysphagia in Patients With Multiple Sclerosis: a Randomized Triple-Blind Placebo-Controlled Clinical Trial

Public title
The Effects of Pyridostigmine on Dysphagia in Patients With Multiple Sclerosis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
A diagnosis of multiple sclerosis is made by a neurologist specialized in multiple sclerosis, based on the 2017 McDonald criteria, and the patient is receiving treatment for multiple sclerosis. After explaining the goals and methods of the study and all the sections of the informed consent form, the patient is willing towards participation and cooperation. The patient has a DYMUS score of at least 3, based on the persian version of the questionnaire.
Exclusion criteria:
Any comorbidity due to previous neurological disorders, e.g. previous cerebrovascular accidents. Other neurological disorders A history of relapse (if MS type is relapsing-remitting) in the previous 3 months. An Expanded Disability Status Scale (EDSS) score above 7.5. Currently being under treatment with pyridostigmine for any reasons. A history of hypersensitivity to anticholinesterase inhibitors or any of the compounds found in our placebo. The patient has mechanical obstruction in intestinal or urinary tract. The patient is currently pregnant or breastfeeding. Dysphagia caused by other disorders than MS. Having a decision to start any other treatment for dysphagia in time of the study, or having started in the last 3 months.
Age
From **18 years** old to **55 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **48**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization will be done by classifying participants into pyridostigmine and placebo groups, using non-stratified block randomization with blocks of 4, containing 2 spots for pyridostigmine and 2 spots for placebo each. A computer generated list will be prepared, which will have letters "A" and "B" assigned to each group of pyridostigmine or placebo. Then an ID will be assigned to each spot in the blocks in that list, using a combination of 4 English characters (digits or letters, e.g. T1D8). The same IDs will be put on drug containers. Study conductors will use an ordered list of these IDs and will deliver the participants their IDs and and the corresponding drug containers, based on the order of IDs list and the order of participation.
Blinding (investigator's opinion)
Triple blinded
Blinding description
In order to make this study triple blinded, all the steps of block randomization will be done by a person who is not involved in this study, which consists of preparing the computer generated randomized list, computer generated IDs, assigning the IDs to blocks and preparing the order of IDs. These IDs will be put on the containers and then the container will be filled with either pyridostigmine or placebo, in regards with their position in the blocks (A or B) by the same person. Then the containers will be passed to study conductors along with the order of the IDs. Thus the participants, researchers, neurologists, and data analysts will be fully blinded. The list that decrypts whether each ID has received placebo or pyridostigmine will be received and opened at the end of the study and only after complete analysis of results.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Sina Hospital
Street address
Sina Hospital, Hasan Abad Sq.,Imam Khomeini Ave., 12th district
City
Tehran
Province
Tehran
Postal code
1136746911
Approval date
2023-09-03, 1402/06/12
Ethics committee reference number
IR.TUMS.SINAHOSPITAL.REC.1402.072

Health conditions studied

1

Description of health condition studied
Multiple Sclerosis
ICD-10 code
G35
ICD-10 code description
Multiple sclerosis

2

Description of health condition studied
Dysphagia
ICD-10 code
R13.1
ICD-10 code description
Dysphagia

Primary outcomes

1

Description
Patient's score based on the Persian version of DYMUS questionnaire
Timepoint
In the beginning of the study, and after 1 and 3 weeks of intervention
Method of measurement
Persian version of DYMUS questionnaire

Secondary outcomes

1

Description
Patient's score based on the Persian version of EAT-10 questionnaire
Timepoint
In the beginning of the study, and after 1 and 3 weeks of intervention
Method of measurement
Persian version of EAT-10 questionnaire

2

Description
Patient's score based on the Persian version of SWAL-QOL questionnaire
Timepoint
In the beginning of the study, and after 3 weeks of intervention
Method of measurement
Persian version of SWAL-QOL questionnaire

Intervention groups

1

Description
Intervention group: pyridostigmine tablet. The duration of intervention is 3 weeks. For the first 4 days of the study, this group will have half a 60 mg tablet of pyridostigmine, three times a day, 30 minutes before breakfast, lunch and dinner. During the following 3 days (until the end of first week), the dose before lunch is increased to a complete 60 mg tablet. In the next 3 days, the patient will have the dose before breakfast increased to a complete tablet, and then after that will continue on a 60 mg dose of pyridostigmoine, PO, three times a day, until the end of third week.
Category
Treatment - Drugs

2

Description
Control group: placebo tablet. The duration of intervention is 3 weeks. For the first 4 days of the study, this group will have half a 60 mg tablet of placebo, three times a day, 30 minutes before breakfast, lunch and dinner. During the following 3 days (until the end of first week), the dose before lunch is increased to a complete 60 mg tablet. In the next 3 days, the patient will have the dose before breakfast increased to a complete tablet, and then after that will continue on a 60 mg dose of placebo, PO, three times a day, until the end of third week. The dosage of placebo group is completely similar to the one of the pyridostigmine group.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
MS research center, Sina hospital, Tehran University of Medical Sciences
Full name of responsible person
Dr. MohammadAli Sahraian
Street address
Sina Hospital, Hasan Abad Sq., Imam Khomeini Ave., 12th District
City
Tehran
Province
Tehran
Postal code
1136746911
Phone
+98 21 6634 8500
Email
sahraian1350@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Dr. MohammadAli Sahraian

Street address
Tehran University of Medical Sciences, Poursina St., 16 Azar St., Keshavarz Blvd.

City
Tehran

Province
Tehran

Postal code
1136749986

Phone
+98 21 6634 8571

Email
sahraian1350@yahoo.com

Grant name

Grant code / Reference number

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

Title of funding source
Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Majid Hamidi

Position
Researcher

Latest degree
Medical doctor

Other areas of specialty/work
General Practitioner

Street address
MS Research Institute, Sina Hospital, Hasan Abad Sq., Imam Khomeini Ave., 12th District

City
Tehran

Province
Tehran

Postal code
1136746911

Phone
+98 21 6634 8500

Email
hamidi.majid.96@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Dr. MohammadAli Sahraian

Position
Professor

Latest degree
Medical doctor

Other areas of specialty/work
Neurology

Street address
Sina Hospital, Hasan abad Sq., Imam Khomeini Ave., 12th District

City
Tehran

Province
Tehran

Postal code
1136746911

Phone
+9866348500

Email
sahraian1350@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Dr. MohammadAli Sahraian

Position
Professor

Latest degree
Medical doctor

Other areas of specialty/work
Neurology

Street address
Sina Hospital, Hasan Abad Sq., Imam Khomeini Ave., 12th District

City
Tehran

Province
Tehran

Postal code
1136746911

Phone
+98 21 6634 8571

Email
sahraian1350@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to

make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

No more information

When the data will become available and for how long

6 months after publication of results.

To whom data/document is available

No more information

Under which criteria data/document could be used

No more information

From where data/document is obtainable

Email address: sahraian1350@yahoo.com

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

Sending a request email

Comments