

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Investigation on the effect of texture-modified diet on dietary intake and nutritional status in stroke patients with dysphagia receiving neuromuscular electrical stimulation and traditional dysphagia therapy

Protocol summary

Study aim

Examining of the effect of texture-modified diet on dietary intake and nutritional status in stroke patients with dysphagia

Design

Randomization is done individually. The entry of each patient into the intervention or control group is done randomly and with the help of 4 blocks. This is done by using a reliable website to generate random numbers.

Settings and conduct

This clinical trial will be conducted in patients referred to the neurology ward of Al-Zahra Hospital (S). Diet with modified tissue is provided to stroke patients receiving neuromuscular electrical stimulation and traditional swallowing therapy. Patients will not be aware of the type of intervention.

Participants/Inclusion and exclusion criteria

Inclusion factors chronic stroke patients with swallowing disorder the age between 50-70 years presence of dysphagia Non-inclusion factors presence of dysphagia before stroke feeding with tube sever liver disease

Intervention groups

1. texture-modified diet+neuromuscular electrical stimulation+traditional dysphagia therapy 2. neuromuscular electrical stimulation+traditional dysphagia therapy 3. texture-modified diet+traditional dysphagia therapy 4. traditional dysphagia therapy

Main outcome variables

Before and after studying the nutritional status and dietary intake and swallowing performance of the patients, respectively, they are checked using the short nutritional assessment scale, Nutritionist 4 software, and the dysphagia severity and outcome scale.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201129049534N7**
Registration date: **2023-04-15, 1402/01/26**
Registration timing: **registered_while_recruiting**

Last update: **2023-04-15, 1402/01/26**

Update count: **0**

Registration date

2023-04-15, 1402/01/26

Registrant information

Name

Mohammad bagherniya

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 3183

Email address

bagherniya@nutr.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-04, 1402/01/15

Expected recruitment end date

2023-08-23, 1402/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation on the effect of texture-modified diet on

dietary intake and nutritional status in stroke patients with dysphagia receiving neuromuscular electrical stimulation and traditional dysphagia therapy

Public title

effect of texture-modified diet in stroke patients with dysphagia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

chronic stroke patients with swallowing disorder the age between 50-70 years presence of dysphagia

Exclusion criteria:

presence of dysphagia before stroke feeding with tube sever liver disease

Age

From **50 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

After sampling in an easy or accessible way, random allocation of samples is done using the blocking method (4 blocks based on age and sex) and individually. This is done using a reputable random number making website: <https://www.sealedenvelope.com/simple-randomiser/v1/lists> First, we identify one letter for each group, for example, group A (intervention group 1), group B (intervention group 2), group C (intervention group 3) and group D (intervention group 4), and thus four groups named A and B and C and D will be formed and each research unit will be given a number according to the sample size of one list of 80 people will be obtained, which will be placed in each group of 20 people. Using the website and considering the four blocks, a list consisting of the letters A and B and C and D will be prepared randomly. Each participant will be assigned to one of the groups.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Hezar Jerib street

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2023-02-27, 1401/12/08

Ethics committee reference number

IR.MUI.RESEARCH.REC.1401.376

Health conditions studied

1

Description of health condition studied

dysphagia

ICD-10 code

I63

ICD-10 code description

Cerebral infarction

Primary outcomes

1

Description

nutritional status

Timepoint

before treatment, end of first,second,third and fourth weeks and one month after intervention

Method of measurement

Minimal nutritional assessment

2

Description

Dietary intake

Timepoint

before treatment, end of first,second,third and fourth weeks and one month after intervention

Method of measurement

Nutritionist 4 software

Secondary outcomes

1

Description

Swallowing capability

Timepoint

before treatment, end of first,second,third and fourth weeks and one month after intervention

Method of measurement

Intervention groups

1

Description

Intervention group 1: Will receive a texture-modified diet that includes changing the concentration of liquids and softening solid foods to make them easier to swallow, along with electrotherapy including neuromuscular electrical stimulation with a frequency of 10 Hz for 20 minutes per session to strengthen the muscles of the laryngeal area as well as traditional swallowing therapy.

Category

Rehabilitation

2

Description

Intervention group 2: will receive electrotherapy including neuromuscular electrical stimulation with a frequency of 10 Hz for 20 minutes per session to strengthen the muscles of the laryngeal area and traditional swallowing therapy.

Category

Rehabilitation

3

Description

Intervention group 3: will receive a texture-modified diet that includes changing the concentration of liquids and softening solid foods to make them easier to swallow, along with traditional swallowing therapy.

Category

Rehabilitation

4

Description

Intervention group 4: will receive only traditional swallowing therapy.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital

Full name of responsible person

Mohammad Baghernia

Street address

Al-Zahra Hospital,Sofeh street,Isfahan,Iran

City

Isfahan

Province

Isfahan

Postal code

81746-75731

Phone

+98 31 3668 5555

Email

bagherniya@nutr.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Gholamreza Askari

Street address

Hezar-jerib Ave, Isfahan University of Medical Sciences,Isfahan University of Medical Sciences,Isfahan,Iran

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3668 7898

Email

bagherniya@nutr.mui.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Mohammad baghernia

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Hezar-jerib Ave, Isfahan University of Medical Sciences, Isfahan University of Medical Sciences, Isfahan, Iran

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Phone

+98 31 3668 7898

Email

bagherniya@nutr.mui.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mohammad baghernia

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Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

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Hezar-jerib Ave, Isfahan University of Medical Sciences, Isfahan University of Medical Sciences, Isfahan, Iran

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Phone

+98 31 3668 0048

Email

bagherniya@nutr.mui.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Because of privacy of findings of study

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available