Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

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Iran (Islamic Republic of)

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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
Isfehan
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

Dysphagia Outcome and Severity Scale

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
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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
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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
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
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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