Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Nov 2026

The Effect of Multiple Nursing Interventions on the Incidence of Stroke Associated Pneumonia in Patients

Protocol summary

Study aim
Determining the effect of multiple nursing interventions on the incidence of pneumonia -dependent stroke

Design
The randomized clinical trial with intervention and control groups was used for randomization from the randomization site.

Settings and conduct
Department of Neurology, Ali Bin Abitalib Hospital affiliated to Zahedan University of Medical Sciences from the time of patient admission and taking into account the entry criteria in eligible patients for four consecutive days and at least twice a day After the implementation of the mentioned care package, the symptoms including the presence or absence of fever, cough, changes in the number of white blood cells and the final diagnosis of the neurologist will be examined by the relevant tools and finally the occurrence of this complication will be announced by him.

Participants/Inclusion and exclusion criteria
Detecting confirmation of ischemic stroke by a specialist physician, Moderate or intense dysphagia in accordance with the GUSS(Gugging Swallowing Screen) tool;Age older than 18, 24 hours after the onset of ischemic stroke symptoms, National Institutes of Health Stroke Scale(NIHSS) score above 3,Direct acceptance of the patient from the emergency department or the patient's direct referral to the doctor's office;The presence of pneumonia before hospitalization, Patients with liver and kidney failure, Allergies to chlorhexidine, Oral surgery, Patients with immune system suppression, Any malnutrition, Dissatisfaction to participate in the study

Intervention groups
In this study of two tools including GUSS for dysphagia and The International Dysphasia Diet Standardization Initiative(IDDSI) to provide a diet based on the intensity of dysphagia; And the oral care checklist will be used in the patients' patients. The control group will receive the usual sector care.

Main outcome variables
Stroke related pneumonia

General information

Reason for update

Acronym
SAP

IRCT registration information
IRCT registration number: **IRCT20240212060983N1**
Registration date: **2024-05-23, 1403/03/03**
Registration timing: **registered_while_recruiting**

Last update: **2024-05-23, 1403/03/03**
Update count: **0**

Registration date
2024-05-23, 1403/03/03

Registrant information

Name
Asma Rostami

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 54 3344 0566

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nrsasma1155@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-05-21, 1403/03/01

Expected recruitment end date
2024-11-21, 1403/09/01

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Multiple Nursing Interventions on the Incidence of Stroke Associated Pneumonia in Patients

Public title

Investigating the effect of multiple nursing interventions on ischemic stroke-related pneumonia

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Detecting confirmation of ischemic stroke by a specialist physician Moderate or intense dysphagia (in accordance with the GUSS tool score 0-14) Age older than 18 24 hours after the onset of ischemic stroke symptoms NIHSS score above 3 Direct acceptance of the patient from the emergency department or the patient's direct referral to the doctor's office and then referred to the department

Exclusion criteria:

Presence of pneumonia before hospitalization Patients with liver and kidney failure Infectious patients Patients in need of specialized oral care and evaluation Allergy to chlorhexidine Oral surgery Gum diseases Infectious diseases of the mouth Patients with immunosuppression Having any malignancy Lack of consent to participate in the study

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, patients are divided into two control and intervention groups based on the random assignment of quadruple blocks; Regarding the equal placement of the samples in the two control and intervention groups, a limited randomization method called blocking was used. This method helps this study so that in cases where intermediate analyzes are needed during the sampling process, the number of samples allocated to each of the studied groups is equal. In this study, the size of all blocks is equal. In this study, online randomization was used to generate random sequences. The decision to accept or reject participation in the study is made first and the informed consent form is completed, and then the participants are randomly assigned to each group.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Joint Organizational Ethics Committee of Nursing and Midwifery Faculty and Rehabilitation Faculty of

Street address

No.4, Mazari 19, Mazari Boulevard

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9817747843

Approval date

2024-01-30, 1402/11/10

Ethics committee reference number

IR.TUMS.FNM.REC.1402.197

Health conditions studied

1

Description of health condition studied

Ischemic stroke

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Stroke-related pneumonia

Timepoint

Before the implementation of the intervention and then 4 days after the end of the intervention

Method of measurement

Ischemic stroke-related pneumonia instrument

Secondary outcomes

empty

Intervention groups

1

Description

In order to collect the necessary data for the study, three tools and a checklist will be used; With the help of these tools and checklist, patients' conditions are accurately

evaluated and then based on the results, appropriate nursing care is provided for each patient's condition. Tool number one (GUSS) consists of two tests; The test starts with swallowing saliva and then continues with swallowing semi-solid, liquid and solid tissues respectively. Instrument number two (IDDSI) consists of two components: food and beverage component; The nutritional strategy will be chosen by the nurse based on the severity of dysphagia, for example, in moderate dysphagia, feeding will be through a nasogastric tube and the use of pureed food, and in severe dysphagia, the patient will be given fasting and supplements through a nasogastric tube. will be. Oral care will be done using a ten-step checklist. In this study, nursing interventions to affect the occurrence of pneumonia related to ischemic stroke will include the examination of the severity of dysphagia, strategies related to diet and oral care methods in this group of patients after a detailed evaluation of the parameters of the tools and the above checklist. After the implementation of the mentioned care package, in this study, in order to evaluate stroke-related pneumonia, the developed symptoms include the presence or absence of fever, cough and white blood cells equal to and greater than 10x109 per liter or white blood cells equal to and smaller than 4 x 109 per liter and the final diagnosis of the neurologist will be examined by the stroke-related pneumonia tool and finally the occurrence of SAP will be announced by him.

Category

Prevention

2

Description

Control group: will receive routine ward care for four consecutive days.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali ibn Abi Talib hospital

Full name of responsible person

Kaveh Yazdani

Street address

Ali Ibn Abitalib Hospital,Major General Mohammad Mir St., Persian Gulf Highway

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Ali akbari Sari

Street address

6th floor, Central Organization of Tehran University of Medical Sciences, corner of Qods St.,Keshavarz Boulevard

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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

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

Asma Rostami

Position

Master's student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Maryam Esmaeili

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Person responsible for updating data

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Latest degree
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Other areas of specialty/work
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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
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be 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