Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Nov 2026

Investigation of The Effect Of Care Plan On Post Stroke Constipation Frequency

Protocol summary

Study aim
Assesment of the effect of a care program on the frequency of constipation following stroke in patients admitted to Alzahra Hospital in 2018

Design
In two groups, the test and control using the random number table and closing the eyes and putting the finger on one of the numbers will be the number. To move horizontally to the right, next to the top and then to the left of the table will be the number of patient beds in the two groups of test and control (66 to control and 66 to the case group).

Settings and conduct
In this research, the samples will be selected initially in a simple continuity method, which will be among the patients admitted to the intensive care units 2, the stroke unit and the internal nerves section of Al Zahra Hospital, which will have acceptable conditions for entry into the research. They will be elected to the desired level

Participants/Inclusion and exclusion criteria
inclusion criteria: Patients who are suffering from constipation following of stroke that admitted to the hospital are enrolled in the study Exclusion criteria: Patient's death

Intervention groups
The first group includes patients with constipation receiving a new nursing care program. The second group includes patients who receive routine care.

Main outcome variables
Post Stroke Constipation

General information

Reason for update

Acronym
CPSC

IRCT registration information
IRCT registration number: **IRCT20181008041273N1**
Registration date: **2019-03-10, 1397/12/19**
Registration timing: **registered_while_recruiting**

Last update: **2019-03-10, 1397/12/19**
Update count: **0**

Registration date
2019-03-10, 1397/12/19

Registrant information

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Name of organization / entity

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-10-23, 1397/08/01

Expected recruitment end date
2019-03-19, 1397/12/28

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigation of The Effect Of Care Plan On Post Stroke Constipation Frequency

Public title
The Effect Of Care Plan On Post Stroke Constipation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients are examined by a neurologist and their illness is confirmed. The patient (if he / she is alert) or his / her companion will have informed consent to participate in the study. Patients do not have concurrent participation in another study. The doctor will allow the patient to participate in this study. Being over 18 years old. After a stroke, have been admitted for at least one week Having constipation according to Rome's criterion (having at least two criteria)

Exclusion criteria:

No history of chronic constipation before a stroke, in which the patient has referred to a doctor or has received a medication. No history of malignant tumors, colon diseases like irritable bowel, etc. Based on a patient report and information contained in the case Lack of water and electrolyte imbalance due to kidney problems

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **132**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation of patients to intervention and control groups by random block method

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

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

hezarjarib

City

isfahan

Province

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Postal code

8174673461

Approval date

2018-11-14, 1397/08/23

Ethics committee reference number

IR.MUI.RESEARCH.REC.1397.320

Health conditions studied

1

Description of health condition studied

stroke

ICD-10 code

I66.0

ICD-10 code description

Occlusion and stenosis of middle cerebral artery

Primary outcomes

1

Description

constipation frequency according Bristol scale

Timepoint

before, discharge time, one month after discharge

Method of measurement

rome IV, Bristole

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group includes patients who undertake a water and electrolyte correctional nursing program, modify the diet, control medicine, massage therapy, train patients during discharge and follow up. care

Category

Other

2

Description

Control group: Includes patients who receive routine care

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospita

Full name of responsible person

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Sponsors / Funding sources

1

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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
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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