Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of response to two regimens of Lactolose and Bisacodyl in the treatment of acute constipation in patients with acute stroke

Protocol summary

Study aim

Determination of the response rate to the drug (lactulose, bisacodyl) in acute cerebral stroke patients with acute constipation

Design

A clinical trial with community-based and pragmatic control group, with parallel and single blind, randomized, 45 patients in the control group and 45 patients in the intervention group will be included.

Settings and conduct

This is an interventional study on 45 patients with acute stroke. Patients will be checked on the second day after admission and will be questioned for the presence of defecation. Patients with constipation will randomly be assigned to either 30 ml or 20 gr lactulose or 10 mg bisacodyl pill. Patients will be evaluated for defication during the duration of admission (on average 5 days) and will be evaluated with the phone call if they are cleared earlier.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with acute stroke (Diagnosed by a neurologist and confirmed by MRI or CT-Scan) who had new onset constipation during 48 hours. Exclusion criteria: - Previous history of chronic constipation or incontinence - Previous history of colon or rectum cancer - Metabolic cause of constipation (eg. Hypokalemia) - Taking drugs induced constipation (eg. Anticholinergics or drugs with anticholinergic effects, calcium channel blockers and etc.) - Previous history of diabetes mellitus or hypothyroidism - Previous history of stroke and new symptoms due to metabolic derangement or acute infection

Intervention groups

Intervention group: Patients receiving Bisacodyl Control group: Patients receiving Lactulose

Main outcome variables

Constipation improvement and response to treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181009041286N1**
Registration date: **2019-01-17, 1397/10/27**
Registration timing: **retrospective**

Last update: **2019-01-17, 1397/10/27**
Update count: **0**

Registration date

2019-01-17, 1397/10/27

Registrant information

Name

reza Daneshvar kakhki

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5554 0026

Email address

daneshvar-r@mail.kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-22, 1396/10/01

Expected recruitment end date

2018-07-23, 1397/05/01

Actual recruitment start date

2017-12-22, 1396/10/01

Actual recruitment end date

2018-07-23, 1397/05/01

Trial completion date

2018-08-01, 1397/05/10

Scientific title

Comparison of response to two regimens of Lactolose and Bisacodyl in the treatment of acute constipation in patients with acute stroke

Public title
The effects of laxative drugs in the treatment of acute constipation in patients with acute stroke
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Admission within 48 hours of onset of symptoms Definite stroke diagnosis and confirmation with CT-Scan or MRI Acute constipation
Exclusion criteria:
Patients with constipation before stroke History of colon or rectum cancer Constipation caused by metabolic disorder such as hypokalemia Taking drugs that cause constipation, such as anticholinergic drugs or drugs with anticholinergic effects, calcium blockers, etc. History of diabetes mellitus History of myocardial infarction History of hypothyroidism
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked

- Participant

Sample size
Target sample size: **50**
Actual sample size reached: **45**
Randomization (investigator's opinion)
Randomized
Randomization description
Selecting groups is completely random and will be done after matching. Randomization of patients will be done by file number using www.random.org site. On this site, the Gaussian randomization method was used with the normal distribution.
Blinding (investigator's opinion)
Single blinded
Blinding description
The Lactulose and Bisacodyl drugs are used in the same way with the same bottle, and patients will not be informed of the type of medication they receive.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Kashan University of Medical Science
Street address
Pezeshk St., Ghotbe Ravandei ave.
City
Kashan
Province
Isfehan
Postal code
87159/81151
Approval date
2017-02-08, 1395/11/20
Ethics committee reference number
IR.KAUMS.REC.1395.047

Health conditions studied

1

Description of health condition studied
Acute constipation
ICD-10 code
K59.0
ICD-10 code description
Constipation

Primary outcomes

1

Description
Defication
Timepoint
Daily check for defication after taking drug
Method of measurement
Questionnaire designed by researcher

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group (Bisacodyl): Patients will receive 10 mg daily and will be evaluated for at least 5 days for response to treatment.
Category
Treatment - Drugs

2

Description
Control group (Lactulose): Patients will receive 20 gr equal to 15 ml syrup of lactulose daily and will be evaluated for at least 5 days for response to treatment.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Kashan Shahid Beheshtei hospital
Full name of responsible person
Reza Daneshvar Kakhki
Street address
Pezesh st., Ghotb e Ravandei ave.
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8715981151
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Dr. Hamidreza Banafshe
Street address
Pezesh st., Ghotb e Ravandei Ave.
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8115187159
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Email
banafshe57@hotmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kashan 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
Kashan University of Medical Sciences
Full name of responsible person
Reza Daneshvar kakhki
Position
Assistant professor
Latest degree
Medical doctor
Other areas of specialty/work
Neurology
Street address
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Person responsible for updating data

Contact

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Reza Daneshvar kakhki

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Assistant professor

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is 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
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
demographic data and outcome after deidentification will be available

When the data will become available and for how long
Data will be available from 2019 for 1 year

To whom data/document is available
For academic researchers, data will be available

Under which criteria data/document could be used
The use of data will be subject to obtaining a license from the University's Research and Technology Dept.

From where data/document is obtainable
neurology department, Shahid Beheshti General Hospital, Pezesh St., Ghotbe Ravandi Ave. Postal Code: 8715981151

What processes are involved for a request to access data/document
Information will be obtained from the Department of Research and Technology of the University and correspondence with the Department of Neurology, Shahid Beheshti Hospital of Kashan.

Comments
No