Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of fenugreek seeds on some gastrointestinal disorder in patients with mechanical ventilation

Protocol summary

Summary

This study will investigate the effect of fenugreek seeds on gastrointestina disorder in patients with mechanical ventilation hospitalized in intensive care units. A total of sixty patients; ged 15-80 years old; who are admitted in ICU due to any medical or surgical problem; will be randomly assigned into intervention or control group. All of the patients will be gavaged with standard food for five days.The patients in the control group will receive food is just as routine. Gastric residual volume GRV; the incidence of regurgitation; diarrhea; constipation; abdominal sounds; and ileus; gastrointestinal bleeding; bloating and abdominal distension and daily measurement. will be measured daily for five days and compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016021126511N1**
Registration date: **2016-05-06, 1395/02/17**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-05-06, 1395/02/17

Registrant information

Name
Azam Zarghi
Name of organization / entity
Sabzevar University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 51 4466 0944
Email address
zarghia92@medsab.ac.ir

Recruitment status

Recruitment complete

Funding source

Sabzevar University of Medical Sciences

Expected recruitment start date

2015-10-22, 1394/07/30

Expected recruitment end date

2016-04-19, 1395/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of fenugreek seeds on some gastrointestinal disorder in patients with mechanical ventilation

Public title

The effect of fenugreek seeds on some gastrointestinal disorder in patients with mechanical ventilation.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: patients with informed consent to participate in research; mechanical ventilation; nasogastric tube feeding (NGT); age15-80 years old; hemodynamic stability; Absence of pancreatitis, severe renal failure; severe hypothyroidism; hyperparathyroidism diseases and pregnancy; Non is history partial or total gastrostomy and Food allergies.
Exclusion criteria: Parents patient's or patient's refusal to continue participate in research; Patients who do not tolerate gavage; INR>2; patient died during the study.

Age

From **15 years** old to **80 years** old

Gender

Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size:
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Sabzevar University of Medical Sciences
Street address
Building number two, Vice Chancellor for Education, University of Sabzevar
City
Sabzevar
Postal code
2264462
Approval date
2015-12-28, 1394/10/07
Ethics committee reference number
IR.MEDSAB.REC.1394.128

Health conditions studied

1

Description of health condition studied
Cerebrovascular diseases
ICD-10 code
I63, I65,
ICD-10 code description
Cerebral infarction, Occlusion and stenosis of precerebral arteries, not resulting in cerebral infarction , Other cerebrovascular diseases

2

Description of health condition studied
Chronic lower respiratory diseases
ICD-10 code
J40, J41,
ICD-10 code description
Chronic lower respiratory diseases

3

Description of health condition studied
Hypertensive diseases
ICD-10 code
I10, I11,
ICD-10 code description
Essential (primary) hypertension , Hypertensive heart disease ,Secondary hypertension

4

Description of health condition studied
Diseases of the nervous system
ICD-10 code
G35
ICD-10 code description
Demyelinating diseases of the central nervous system

5

Description of health condition studied
Ischaemic heart diseases
ICD-10 code
I23. I25
ICD-10 code description
Chronic ischaemic heart disease, Chronic ischaemic heart disease,

6

Description of health condition studied
Diseases of the circulatory system
ICD-10 code
163, 166
ICD-10 code description
Cerebral infarction

7

Description of health condition studied
Diabetes Mellitus
ICD-10 code
E10-E14
ICD-10 code description
Diabetes Mellitus

Primary outcomes

1

Description
gastric residual volume
Timepoint
Every 3 hrs exactly before doing gavage
Method of measurement
by using 50cc gavage syringe

2

Description

The frequency of bowel movements

Timepoint

Every 24 hours

Method of measurement

Based on the registration number of daily excretion in patient chart

3

Description

Abdominal bloating and distension

Timepoint

Every 24 hours

Method of measurement

Measuring Abdominal circumference to Using a tape measure in centimeter and touching stiffness abdominal to hands and auscultation sounds with stethoscope

4

Description

regurgitation

Timepoint

Every 24 hours

Method of measurement

Based on the regurgitation number of daily excretion in patient chart

5

Description

abdominal sounds

Timepoint

Every 24 hours

Method of measurement

Listen to the sounds of each of the four quadrants of the abdomen with a stethoscope in 5 minutes once a day

6

Description

gastrointestinal bleeding

Timepoint

Every 24 hours

Method of measurement

Sighting vomiting blood, disposal of light bleeding and similar to coffee grounds from the nasogastric tube , black and tarry stools , loss of hemoglobin 2 g over 48 hours without bloodshed another, guaiac test is positive. (check hemoglobin routinely performed and recorded in the sector)

Secondary outcomes

empty

Intervention groups

1

Description

in the intervention group will receive 3mg fenugreek seeds through NGT, twice a day, will be added to the special food for the feeding via NG tube for five days.

Category

Treatment - Drugs

2

Description

in The control group was routinely given special food only / no action

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Emdad Hospital,Sabzevar

Full name of responsible person

Azam Zarghi

Street address

Sabzevar University of Medical Sciences

City

Sabzevar

2

Recruitment center

Name of recruitment center

Waseii Hospital, Sabzevar

Full name of responsible person

Azam Zarghi

Street address

Sabzevar University of Medical Sciences

City

Sabzevar

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Musa Al-Reza Taday'oun far

Street address

Building number two, Vice Chancellor for Education, Sabzevar University of Medical Sciences and Health Services

City

Sabzevar

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Sabzevar University of Medical Sciences

Proportion provided by this source

100

Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Sabzevar University of Medical Sciences
Full name of responsible person
Zarghi Azam
Position
Student of Critical Care Nursing
Other areas of specialty/work
Street address
Building number two, Vice Chancellor for Education, University of Sabzevar
City
Sabzevar
Postal code
9613873136
Phone
+98 51 4466 0944
Fax
+98 514445648
Email
a.zarghi59@gmail.comebrazi.ali@chmail.irZarghiA92@Medsab.ac.ir
Web page address
https://mail.medsab.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Sabzevar University of Medical Sciences
Full name of responsible person
Akram kooshki
Position
Building number two, Vice Chancellor for Education, University of Sabzevar
Other areas of specialty/work
Street address
Ph.D. in Nutrition Sciences
City
Sabzevar
Postal code
9613873136
Phone
+98 51 4444 6070
Fax
+98 514445684
Email
akooshki.nutr@yahoo.com
Web page address
https://mail.medsab.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Sabzevar University of Medical Sciences
Full name of responsible person
Zarghi Azam
Position
Student of Critical Care Nursing
Other areas of specialty/work
Street address
Building number two, Vice Chancellor for Education, University of Sabzevar
City
Sabzevar
Postal code
9613873136
Phone
+98 51 4466 0944
Fax
+98 514445648
Email
a.zarghi59@gmail.comebrazi.ali@chmail.irZarghiA92@Medsab.ac.ir
Web page address
https://mail.medsab.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty