

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 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 gastrointestinal disorder in patients with mechanical ventilation hospitalized in intensive care units. A total of sixty patients; aged 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 as 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

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Iran (Islamic Republic of)

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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); age 15-80 years old; hemodynamic stability; Absence of pancreatitis, severe renal failure; severe hypothyroidism; hyperparathyroidism diseases and pregnancy; Non is history partial or total gastrectomy 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

I63, I66

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

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Person responsible for general inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Position

Student of Critical Care Nursing

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Akram kooshki

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Building number two, Vice Chancellor for Education,
University of Sabzevar

Other areas of specialty/work**Street address**

Ph.D. in Nutrition Sciences

City

Sabzevar

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