

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

The effect of Aloe Vera capsule supplementation on prevention of gastrointestinal disorders in mechanically ventilated patients.

Protocol summary

Study aim

Determine the effect of Aloe vera capsule on gastrointestinal disorders in patients undergoing mechanical ventilation

Design

A triple-blind, randomized clinical trial with control group with a sample size of 36 patients.

Settings and conduct

Sampling is performed among patients with mechanical ventilation who are in the ICU section at Sabzevar Hospital. In this study, Participants (because of low level of consciousness), care provider nurse and data analyzer will be blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients undergoing mechanical ventilation, being at the age of 15 years old and over.
Non inclusion criteria: digestive disorders; low blood pressure; active bleeding

Intervention groups

Patients in the intervention group receive one Aloe Vera capsule produced by Iran-Kashan Baraj Essen Company, before gavage at 9 a.m for 5 days. The control group don't receive any intervention.

Main outcome variables

Constipation; ileus; remaining food; abdominal distention; vomiting; the numbers of intestinal sounds; bloody vomiting; bloody lavage; bloody stool

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180723040565N1**

Registration date: **2018-10-12, 1397/07/20**

Registration timing: **registered_while_recruiting**

Last update: **2018-10-12, 1397/07/20**

Update count: **0**

Registration date

2018-10-12, 1397/07/20

Registrant information

Name

Ezat Javanshir

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 58 3634 6057

Email address

ezat_javanshir@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-06, 1397/06/15

Expected recruitment end date

2018-10-22, 1397/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Aloe Vera capsule supplementation on prevention of gastrointestinal disorders in mechanically ventilated patients.

Public title

The effect of Aloe Vera capsule supplementation on prevention of gastrointestinal disorders

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Undergoing mechanical ventilation in ICU Feeding the patient through the gastric tube Being at the age of 15 years or more Air Conditioning Mode SIMV Having informed consent of patient protector, regarding the patients participation in the research. Air Conditioning Mode SIMV Having informed consent of patient's protector, regarding the patient's participation in the research.

Exclusion criteria:

Having any surgery in the digestive system. Having a history of stomach ulcers or duodenal ulcers. Having active bleeding. Having food allergy or allergy to Aloe vera Being Pregnant. Undergoing chemotherapy. Being addict Diagnosis of the doctor to change the type and dosage of the patient's laxative Diagnosis of the doctor to change the patient's ventilation mode Diagnosis of the physician based on changing the dose and type of sedation and salivation drugs Hypothyroidism

Age

From **15 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size

Target sample size: **36**

Randomization (investigator's opinion)

Randomized

Randomization description

Permutation blocks will be used for randomization.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Participants (because of low level of consciousness), care provider nurse and data analyzer will be blind.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Sabzevar University of Medical Sciences

Street address

Block B,Campus of Sabzevar University of Medical Sciences, road of Toohid city, Sabzevar

City

Sabzevar

Province

Razavi Khorasan

Postal code

94617-85493

Approval date

2018-08-21, 1397/05/30

Ethics committee reference number

IR.MEDSAB.REC.1397.025

Health conditions studied

1

Description of health condition studied

Patients under mechanical ventilation

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Percentage of people with constipation

Timepoint

Everyday (9 a.m, 3 p.m, 9 p.m) for 5 days

Method of measurement

stethoscope

2

Description

Percentage of people with vomiting

Timepoint

Everyday (9 a.m, 3 p.m, 9 p.m) for 5 days

Method of measurement

Counting the number of gas

3

Description

Percentage of people with diarrhea

Timepoint

Everyday (9 a.m, 3 p.m, 9 p.m) for 5 days

Method of measurement

Number of pads consumed

4

Description

The percentage of people with a residual stomach volume of more than 150 cc

Timepoint

Everyday (9 a.m, 3 p.m, 9 p.m) for 5 days

Method of measurement

50cc syringe

5

Description

Percentage of people with bloating
Timepoint
Everyday (9 a.m, 3 p.m, 9 p.m) for 5 days
Method of measurement
Strip meter

6

Description
Percentage of people with ileus
Timepoint
Everyday(9 a.m, 3 p.m, 9 p.m) for 5 days
Method of measurement
stethoscope

7

Description
Percentage of people with reduced intestinal sounds
Timepoint
Everyday (9 a.m, 3 p.m, 9 p.m) for 5 days
Method of measurement
stethoscope

8

Description
Percentage of people with hematochezia
Timepoint
Before intervention and after intervention
Method of measurement
Complete blood count (CBC) test

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: They receive one Aloe Vera capsule produced by Iran-Kashan Baraj Essen Company, before gavage at 9 a.m for 5 days.
Category
Prevention

2

Description
Control group: This group does not receive intervention
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Sabzevar University of Medical Sciences
Full name of responsible person

Mostafa Rad
Street address
Block B, Campus University of Medical Sciences ,
Tohid Shahr Road, Sabzevar
City
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Razavi Khorasan
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info@medsab.ac.ir
Web page address
<http://www.medsab.ac.ir/>

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Sabzevar University of Medical Sciences
Full name of responsible person
Fereshteh Ghorat
Street address
Block B,Campus of Sabzevar University of Medical
Sciences, road of Toohid city, Sabzevar
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Sabzevar
Province
Razavi Khorasan
Postal code
9613873119
Phone
+98 51 4401 1000
Fax
+98 51 4401 1013
Email
info@medsab.ac.ir
Web page address
<http://www.medsab.ac.ir/>
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
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding

Academic

Email

mostafarad633@yahoo.com

Person responsible for general inquiries

Contact

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Mostafa Rad

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for updating data

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Latest degree

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Person responsible for scientific inquiries

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Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

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