

# 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**  
Sabzevar  
**Province**  
Razavi Khorasan  
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**Phone**  
+98 51 4401 1000  
**Fax**  
+98 51 4401 1013  
**Email**  
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  
**City**  
Sabzevar  
**Province**  
Razavi Khorasan  
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**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

**Street address**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

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**Full name of responsible person**

Mostafa Rad

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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## Person responsible for scientific 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

**Street address**

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**City**

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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