

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Study of the effect of nutrition with synbiotic compounds on prevention of gastrointestinal dysfunction in patients undergoing mechanical ventilation

Protocol summary

Study aim

The aim of this study was to evaluate the effect of synbiotic on prevention of gastrointestinal intolerance in patients undergoing mechanical ventilation.

Design

In this study, patients undergoing mechanical ventilation and fed through the nasogastric tube were randomly assigned to experimental and control groups. Patients in the test group will receive a compound of synbiotics with code A and the control group will receive sugar powder with code B. Patients in both groups are fed twice daily for one week. Before the intervention and at the end of each day, the gastric residual volume, intra-abdominal pressure, frequency of defecation, gastrointestinal bleeding, and bowel sounds were measured by a nurse.

Settings and conduct

This study is performed in intensive care units in the hospitals affiliated to the Semnan University of Medical Sciences. Patients and who measure the gastrointestinal dysfunction symptoms are not aware of grouping patients in using the synbiotic.

Participants/Inclusion and exclusion criteria

Patients with age between 30 and 70 years, fed through the nasogastric tube and are connected to the mechanical ventilation for at least one week are included in the study. Patients undergoing gastrointestinal surgery, with malignancy, liver failure and multiple organ failure, body mass index greater than 35 and who take medications that affect on gastrointestinal motility are not included in the study.

Intervention groups

The experimental group receive compound of synbiotic (Lactocare) twice daily (9 am and 9 pm). Control group receive sugar powder twice daily (9 am and 9 pm).

Main outcome variables

Gastric residual volume; Intra-abdominal pressure; times of defecation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110514006481N12**

Registration date: **2019-10-10, 1398/07/18**

Registration timing: **prospective**

Last update: **2019-10-10, 1398/07/18**

Update count: **0**

Registration date

2019-10-10, 1398/07/18

Registrant information

Name

Mohsen Soleimani

Name of organization / entity

Semnan University of Medical Sciences

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Iran (Islamic Republic of)

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solli257@semums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-23, 1398/08/01

Expected recruitment end date

2020-08-22, 1399/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	
Scientific title	Study of the effect of nutrition with synbiotic compounds on prevention of gastrointestinal dysfunction in patients undergoing mechanical ventilation
Public title	Effect of Synbiotic on gastrointestinal dysfunction in patients with mechanical ventilation
Purpose	Prevention
Inclusion/Exclusion criteria	
Inclusion criteria:	Feeding through nasogastric tube. Mechanical ventilation for at least one week.
Exclusion criteria:	Third degree burns Gastrointestinal surgery Multiple organ dysfunction Post cardiac arrest Body mass index more than 35 Liver failure Use of drugs that affect gastrointestinal motility
Age	From 30 years old to 70 years old
Gender	Both
Phase	3
Groups that have been masked	• Participant • Care provider • Outcome assessor
Sample size	Target sample size: 60
Randomization (investigator's opinion)	Randomized
Randomization description	Randomization is done using stratified permuted block randomization. Patients are divided into two strata of addicted and non-addicted. For each stratum, a separate random assignment continues to reach the sample size. For random assignment in each stratum, four blocks of (A, B), which include different states of test and control sequences (AABB, ABAB ...), are used. Block selection is done according to a random digits table.
Blinding (investigator's opinion)	Double blinded
Blinding description	In this study, the researcher puts the compounds of synbiotic and placebo in two containers marked with the letters A and B. The nurse, patient, and who perform evaluation outcome are unaware of the patient grouping.
Placebo	Used
Assignment	Parallel
Other design features	
Secondary Ids	empty

Ethics committees	
1	
Ethics committee	
Name of ethics committee	Semnan University Of Medical Sciences and Health Services
Street address	Semnan university of medical sciences, Shahid Akhlaghi intersection, Basij Blvd., Semnan, Iran.
City	Semnan
Province	Semnan
Postal code	3514799442
Approval date	2019-07-15, 1398/04/24
Ethics committee reference number	IR.SEMUMS.REC.1398.135
Health conditions studied	
1	
Description of health condition studied	Patients undergoing mechanical ventilation; Gastrointestinal dysfunction
ICD-10 code	K59
ICD-10 code description	Other functional intestinal disorders
Primary outcomes	
1	
Description	Gastric residual volume
Timepoint	Before intervention and every day for a week.
Method of measurement	Measure gastric residual volume with syringe.
2	
Description	Intra-abdominal pressure
Timepoint	Before intervention and every day for a week.
Method of measurement	Through the urinary catheter by using a ruler.
3	
Description	Frequency of defecation
Timepoint	Before intervention and every day for a week.
Method of measurement	Count frequency of defecation.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Compound of synbiotic (Lactocare) manufacture of Zeist-Takmir pharmaceutical company, 500 mg twice daily for one week.

Category

Treatment - Drugs

2

Description

Control group: Sugar powder, one teaspoon twice daily for one week.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Koosar Hospital

Full name of responsible person

Mohsen Soleimani

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Koosar hospital, Amin Ave., Basij Blvd., Semnan, Iran.

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2

Recruitment center

Name of recruitment center

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Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Semnan 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

Semnan University of Medical Sciences

Full name of responsible person

Mohsen Soleimani

Position

Associate professor

Latest degree

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Other areas of specialty/work

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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

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available