Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The prophylactic effect of cuminum cyminum extract on gastric residual volume in traumatic patients under ventilator hospitalized in intensive care unit.

Protocol summary

Summary

This is a double-blind, randomized controlled trial with the aim of determining the effect of cumin extract on gastric residual volume in traumatic patients under ventilation in the intensive care unit. Inclusion criteria: traumatic patients with gastric ulcer and under ventilation; more than 24 to 48 hours of ICU admission; non-use of prokinetic drugs. Exclusion criteria: having a recent wound or surgery (10 days or less) on the digestive system; pregnant women; history of allergy to cumin products; intestinal paralysis; use of laxative drugs; abandoning from study and death. The research community includes traumatized patients undergoing mechanical ventilation in the ICU. Sample size consists of 60 patients who will be randomly assigned to randomly assigned random access intervention (cumin) control group (tap water) and the residual gastric volume of the patients will be measured before each intervention and every three hours after the intervention for 4 days.in the intervention group, 6 grams of the extract of cumin in 3 doses will be given to patients ,50 drops to 30 cc of tap water after gavage and patients in the control group daily 30 cc of tap water in 3 divided doses will be given. The residual volume will be measured in two groups every three hours after the intervention. Patients and assessors will not be aware of the type of drug they will receive in order to double-blind.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201610297494N24**
Registration date: **2017-08-18, 1396/05/27**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-08-18, 1396/05/27

Registrant information

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Recruitment status

Recruitment complete

Funding source

Mazandaran University of Medical Sciences.

Expected recruitment start date

2017-09-21, 1396/06/30

Expected recruitment end date

2018-02-19, 1396/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The prophylactic effect of cuminum cyminum extract on gastric residual volume in traumatic patients under ventilator hospitalized in intensive care unit.

Public title

The prophylactic effect of cuminum cyminum extract on gastric residual volume in traumatic patients under

ventilator hospitalized in intensive care unit.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion Criteria: traumatic patients with gastric and venous catheter; aged 18 to 75; passage of more than 24 to 48 hours of ICU admission; non-use of prokinetic drugs such as metoclopramide and erythromycin within 8 hours of intervention. Exclusion criteria: have a wound or recent surgery (10 days or less) on the stomach or gastrointestinal tract; Pregnant women; History of sensitivity to cumin herbs; history of hypothyroidism; history of hypoglycemia; skin sensitivities to cumin products due to The skin effects of the cumin on the body; the onset of intestinal paralysis; the use of laxative drugs; abandoning the study and death.

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

The residual volume is evaluated and recorded by the partner nurse every 3 hours after the intervention for 4 days (except at 3 and 6 o'clock in the morning). Gavage food is considered to be the same for all patients. In both groups the next gavage can be achieved by reaching the residual stomach volume to less than 500 cc. Patients and assessors will not be aware of the type of drug they will receive in order to double-blind. To increase the accuracy and reliability of the work in measuring the residual gastric volumes, six nursing colleagues who are shifting in three shifts are selected (two from each shifts) and the rate of return is recorded on ten patients, thus The reliability between the observers will be recorded by the researcher and then the correlation coefficient between these six will be examined.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Mazandaran University of Medical Science

Street address

Mazandaran University of Medical Sciences, Vice chancellor for research, Moalem street, Moalem square, Sari, Mazandaran, Iran.

City

sari

Postal code

4816715793

Approval date

2017-08-23, 1396/06/01

Ethics committee reference number

IR.MAZUMS.REC.96.10207

Health conditions studied

1

Description of health condition studied

Gastric residual volume

ICD-10 code

K31.9

ICD-10 code description

Disease of stomach and duodenum, unspecified

Primary outcomes

1

Description

Gastric residual volume

Timepoint

Before each feeding, and every three hours after intervention for 4 days, through a gastric tube

Method of measurement

With using a 60 cc gavage syringe.

Secondary outcomes

empty

Intervention groups

1

Description

In the control group,30 cc of tap water every 8 hours will be gavaged (at 9:00,15:00,21:00) after food gavage for 4 days. The residual volume is measured before intervention and every 3 hours after intervention.

Category

Placebo

2

Description

The intervention group will receive cumin cyminum extract (Product of Barij Essen Co, Iran) with a dose of 2 grams every 8 hours, so that 50 drops of cumin are deposited in 30 cc of tap water, then three times a day in (9, 15 and 21 oclock) after food gavage will be gavage by

gavage syringe for 4 days and the residual volume will be measured before starting the gavage and every 3 hours after the start of intervention.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam KHomeini hospital

Full name of responsible person

Dr Masoumeh Bagheri- Nesami

Street address

Emam khomeini hospital,Amir mazandarani Blv, Sari, Mazandaran, Iran

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research Mazandaran University of Medical Sciences

Full name of responsible person

Dr Ahmad Ali Enayati

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Mazandaran University of Medical Sciences, Moalem Street, Moalem Square, Sari, Iran.

City

Sari

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for research Mazandaran 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

Mazandaran University of Medical Sciences

Full name of responsible person

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Position

PHD, faculty member

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Person responsible for updating data

Contact

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