

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of the effect of apple extract and oral drops gastrolit (*Zataria multiflora*) on gastric residual volume and pulmonary aspiration in patients under mechanical ventilation in the Intensive Care Unit of Valiasr hospital of Zanjan in 2020

Protocol summary

Gastric residual volume- Pulmonary aspiration

Study aim

Comparison of the effect of apple extract and oral drops gastrolit (*Zataria multiflora*) on gastric residual volume and Pulmonary aspiration in patients under mechanical ventilation in the Intensive Care Unit of Valiasr hospital of Zanjan in 2019

Design

Patients will be randomly divided into 3 groups using blocking method.

Settings and conduct

The present study will be a single blind randomized clinical trial on patients 18-65 years old with mechanical ventilation requiring gastrointestinal nutrition through gastric catheter admitted in Vali-e-Asr Hospital of Zanjan who have inclusion criteria. Blindness will be such that the study population will not know which group was randomly assigned to one of the three groups.

Participants/Inclusion and exclusion criteria

Patient under mechanical ventilation Hemodynamic stability No history of aspiration when entering the study
Absence of electrolyte disorders affecting gastrointestinal motions such as hypokalemia, hyperglycemia Feeding the nasal-gastric tube or the oral-gastric tube

Intervention groups

The control group will be gavaged after 9 Am, 3 pm and 9 pm with 20 cc of water. In a group gavaged of 8 cc apple extract with 12 cc water immediately after the main meal at 9 am, 3 pm and 9 pm for 5 days The second group will be gavaged with 20 drops of Gastrolith (Thyme essential oil) plus 20 cc water 3 times daily before the main meals at 9 am, 3 pm and 9 pm for 5 days. In each of the three groups, the remaining gastric volume will be measured and recorded before each gavage during the study.

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160818029414N7**

Registration date: **2020-06-22, 1399/04/02**

Registration timing: **retrospective**

Last update: **2020-06-22, 1399/04/02**

Update count: **0**

Registration date

2020-06-22, 1399/04/02

Registrant information

Name

Vahideh Rashtchi

Name of organization / entity

Zanjan university of medical sciences

Country

Iran (Islamic Republic of)

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+98 912 341 1683

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rashtchi@zums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-21, 1398/11/01

Expected recruitment end date

2020-03-19, 1398/12/29

Actual recruitment start date

empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

Comparison of the effect of apple extract and oral drops gastroliit (Zataria multiflora) on gastric residual volume and pulmonary aspiration in patients under mechanical ventilation in the Intensive Care Unit of Valiasr hospital of Zanjan in 2020

Public title

Comparison of the effect of apple extract and oral drops gastroliit (Zataria multiflora) on gastric residual volume and pulmonary aspiration in patients under mechanical ventilation

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patient under mechanical ventilation Hemodynamic stability No history of aspiration when entering the study Absence of electrolyte disorders affecting gastrointestinal motions such as hypokalemia, hyperglycemia Feeding the nasal-gastric tube or the oral-gastric tube

Exclusion criteria:

Having diabetes, pancreatitis, gastrectomy Gastrointestinal bleeding and peptic ulcer Nutrition intolerance Gastrointestinal drugs such as metoclopramide, ondansetron, cisapride and erythromycin Pregnancy

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, patients will be randomly assigned using blocking method.

Blinding (investigator's opinion)

Single blinded

Blinding description

After randomization, we do not tell the patient in which of the three groups. In fact, the interventionist and the analyst are aware of the allocation of groups, but patients do not know in which group they are.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Zanjan University of Medical Sciences

Street address

Zanjan-Azadi Boulevard - First Republic Street - Front of Asian Insurance - Zanjan University of Medical Sciences

City

Zanjan

Province

Zanjan

Postal code

4515613191

Approval date

2020-01-18, 1398/10/28

Ethics committee reference number

IR.ZUMS.REC.1398.428

Health conditions studied

1

Description of health condition studied

Dyspepsia

ICD-10 code

K30

ICD-10 code description

Functional dyspepsia

Primary outcomes

1

Description

Gastric residual volume

Timepoint

Every three hours except 3 in the morning

Method of measurement

Lavender contents of the stomach with a syringe of 60 cc

Secondary outcomes

1

Description

Pulmonary aspiration

Timepoint

On admission to ICU, day 3 and day 5 of the study

Method of measurement

Using a glucose oxidase kit and a ph gauge tape

Intervention groups

1

Description

Intervention group: In the first group will gavage at 9 am, 3 pm and 9 pm, 8 cc apple extract 12 cc water immediately after gavage main meal.

Category

Prevention

2

Description

Intervention group: The second group will gavage 20 drops of Gastrolith (*Zataria multiflora*) plus 20 cc water 3 times daily before the main meals at 9 am, 3 pm and 9 pm for 5 days.

Category

Prevention

3

Description

Control group: The control group will be gavaged after 9 am and 3 pm and 9 pm with gavage meals.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr hospital

Full name of responsible person

Elahe Balaei

Street address

Zanjan - Above Valiasr Square - Sheikh Fazlollah Nouri Highway

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Dr. Alireza Shoghli

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Zanjan University of Medical Sciences, Yousef Sobuti Boulevard, Zanjan, Iran

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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

Zanjan 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

Zanjan University of Medical Sciences

Full name of responsible person

Elahe Balaei

Position

Nursing Graduate Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Master of Science in Nursing

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Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

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