

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Comparing the effect of acupuncture and traditional pharmacologic therapy on Delayed Gastric Emptying on traumatic patient in ICU of BESAT Hospital, Hamadan

Protocol summary

Summary

Objective: Comparing the effect of acupuncture and traditional pharmacologic therapy on Delayed Gastric Emptying on traumatic patient in ICU. Design: Double blind clinical trial. Population: 60 people from traumatic patients (multiple trauma and head trauma) who are admitted in ICU . Inclusion criteria: All trauma patients ranges from 18 to 75 years of age who are admitted in ICU and their conditions suitable for Enteral feeding and have Tube feeding intolerance. Exclusion criteria : Not Satisfied to perform acupuncture, Patients who have contraindications to enteral feeding, age younger than 18 years or older than 75 years, Patients are prohibitive for NG Tube insertion recent major abdominal surgery, , suspected bowel obstruction or perforation, pancreatitis. In the group receiving the drug: Erythromycin 200mg every 6 hours (syrup) will be used as standard drug. If appropriate response is not seen in patients Metoclopramide as supplemental drug dose 10-20 mg every 8 hours will be used. Acupuncture patient groups: stimulation at frequencies between 7 to 13 MA current 7HZ (depending on the patient's wrist width) is performed. The two stimulation for 20 min and at intervals of every 12 hours (twice a day) for 6 days at the P6 acupuncture point and at a depth of 0.5 cm from the skin surface is performed. Improved as the volume of gastric residual volume less than 200 cc in 24 hours - which is obtained through NGTube - is determined in two consecutive days.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201112014578N4**

Registration date: **2012-02-27, 1390/12/08**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-02-27, 1390/12/08

Registrant information

Name

Farshid Rahimibashar

Name of organization / entity

Hamedan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Hamedan University of Medical Sciences-vice chancellor for research

Expected recruitment start date

2012-02-20, 1390/12/01

Expected recruitment end date

2012-11-20, 1391/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of acupuncture and traditional pharmacologic therapy on Delayed Gastric Emptying on traumatic patient in ICU of BESAT Hospital, Hamadan

Public title

The effect of acupuncture and traditional pharmacologic therapy on Delayed Gastric Emptying

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: All trauma patients ranges from 18 to 75 years of age who are admitted in ICU and his conditions suitable for Enteral feeding and has Tube feeding intolerance. postoperative days. Exclusion criteria : Not Satisfied to perform acupuncture Patients who have contraindications to enteral feeding age younger than 18 years or older than 75 years, Patients are prohibitive for NG Tube insertion recent major abdominal surgery, history of partial or total gastrectomy, suspected bowel obstruction or perforation, pancreatitis, administration of prokinetic drugs (Metoclopramide, cisapride, or erythromycin) within the previous 24 hours.

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

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Hamedan University Of Medical Sciences

Street address

Mahdiye Street, Hamedan University Of Medical Sciences

City

Hamedan

Postal code

Approval date

2011-12-10, 1390/09/19

Ethics committee reference number

16/35/9/3244/د/پ

Health conditions studied

1

Description of health condition studied

gastroparesis

ICD-10 code

K31

ICD-10 code description

Other diseases of stomach and duodenum

Primary outcomes

1

Description

Volume remaining in the stomach.

Timepoint

Total volume remaining in the stomach during a day

Method of measurement

Through the NG tube attached to the patient

Secondary outcomes

empty

Intervention groups

1

Description

Acupuncture patient groups: stimulation at frequencies between 7 to 13 mA current 7HZ (depending on the patient's wrist width) is performed. The two stimulation for 20 min and at intervals of every 12 hours (twice a day) for 6 days at the P6 acupuncture point and at a depth of 0.5 cm from the skin surface is performed.

Category

Treatment - Devices

2

Description

In the group receiving the drug: Erythromycine 200mg every 6 hours (syrup) will be used as standard drug. If appropriate response is not seen in patients Metoclopramide as supplemental drug dose 10-20 mg every 8 hours will be used.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital

Full name of responsible person

Dr Farshid Rahimi Bashar

Street address

BESAT Hospital, General ICU, Motahhari

Avenue_Resalat square

City

Hamedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences-vice
chancellor for research

Full name of responsible person

Dr.Heidar Tavilani

Street address

Mahdiye Street, Hamedan University Of Medical
Sciences

City

Hamedan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Hamedan University of Medical Sciences-vice chancellor
for research

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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Farshid Rahimi Bashar

Position

Assistant Professor/Intensive care fellowship

Other areas of specialty/work

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Position

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Other areas of specialty/work

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Web page address

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