Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Jul 2026

Evaluation of the effect of intravenous metoclopramide on gastric emptying in drug-using patients based on ultrasound criteria

Protocol summary

Study aim

Effect of iv metoclopramide on gastric emptying in drug-using patients based on ultrasound criteria

Design

The clinical trial consisted of a control group with parallel groups, a non-randomized phase 3، single blind on 135 patients.the patient will be divided into 3 groups of 45 people.the emergency assistant (clinical caregiver) will select any patient who qualifies for the study and will be in the first group if he or she is a drug user. If he is not a drug user, he will be randomly placed in the second intervention and control group, so that the first person will be in the second iv group and the second person will be in the control group and so on.

Settings and conduct

Randomise patients into opium adiction (D) group or normal group (C),control group (B). all groups will undergo sonography measurements.group (D) will receive 2 cc plasil iv and the (C) Will receive 2 cc of plasil.in group (B) will recieve 2cc n/s in order to placebo The mentioned sonographic variables will be remeasured after 30 minutes in three groups.

Participants/Inclusion and exclusion criteria

Patient age range of 16 to 80 years with BMI less than 35 who have consumed solid food in the last 8 hours or clear liquids in the last 2 hours.Patients with gastrointestinal obstruction, diabetes, a history of gastric surgery or hiatal hernia, or a history of gastrointestinal changes will be excluded.

Intervention groups

Patients divided into 3 groups. The first group of patients with a history of drug use, The second group of patients without a history of drug use and The third group will be the control group. For the first two groups, 10 mg of metoclopramide will be injected intravenously. For the control group, about 2 ml of distilled water of the same volume as metoclopramide will be prescribed

Main outcome variables

Gastric emptying

General information

Reason for update

Acronym

ندارد

IRCT registration information

IRCT registration number: **IRCT20210406050864N1**
Registration date: **2021-11-07, 1400/08/16**
Registration timing: **retrospective**

Last update: **2021-11-07, 1400/08/16**
Update count: **0**

Registration date

2021-11-07, 1400/08/16

Registrant information

Name

Mohamadjavad Yazdipour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4486 7051

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-18, 1400/06/27

Expected recruitment end date

2021-10-19, 1400/07/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluation of the effect of intravenous metoclopramide on gastric emptying in drug-using patients based on ultrasound criteria

Public title
The effect of intravenous metoclopramide on gastric emptying

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
All patients referred to the emergency department between the age of 16 and 80years All patients referred to the emergency department with BMI less than 35 All patients referred to the emergency department with history of opium use All patients who had consumed solid food in the past 8 hours or liquids in the previous 2 hours in the intervention group

Exclusion criteria:
Patients who are unable to have an ultrasound for any reason Patients with a history of diabetes Patients with a history of gastrointestinal surgery Patients with suspected gastrointestinal obstruction Patients taking medication that affects gastrointestinal motility Patients with a history of inflammatory bowel disease Patients with a history of irritable bowel disease

Age
From **16 years** old to **80 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **135**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, participants and the clinical caregiver who is the assistant in charge of the patient will be fully aware of the type of prescription. But the researcher himself, as well as the outcome assessor and data analyst, will be unaware of prescribing to the groups

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics comitte of shahid beheshti university of medical science

Street address
Yaman Street

City
tehran

Province
Tehran

Postal code
1985717443

Approval date
2020-06-30, 1399/04/10

Ethics committee reference number
Ir.sbmu.msp.rec.1399.154

Health conditions studied

1

Description of health condition studied
Effect of methoclopramide on gastric motility

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
gastric emptying

Timepoint
30min

Method of measurement
sonographic criteria

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: will include patients taking opium with a BMI less than 35. Who have consumed solid food in the last 8 hours or consumed clear liquids in the last 2 hours. After obtaining full consent and explanations on how to implement the plan, these patients will be included in the study and will be monitored and recorded at baseline values. These patients undergo ultrasound in both supine and right lateral position (RLP). After recording the measurements, 10 mg (2 cc) of metoclopramide is administered intravenously to patients. The ultrasound is then repeated 30 minutes later and these measurements will be recorded again.

Ultrasound is used to qualitatively examine the material and contents of the stomach (liquid or solid). And antral-gastric grade are classified into three grades: zero, one and two: GRADE 0=absence of fluid GRADE 1 = fluid in RLP position GRAD 2=fluid in both supine and RLP position Quantitative examination will be in the form of Antral cross-sectional area (ACS) and Antral volume measurements. CSA will be calculated by measuring the vertical thickness in the two longitudinal (d1) and anterior-posterior planes (from serosa to serosa) (d2) and using the formula CSA = 3.14 (d1 * d2) 4%. This mathematical model is used to calculate the volume of stomach contents and determine the volume. VOLUME = 27 + (14.6 × RL CSA) _ (1.28 × age)

Category

Treatment - Drugs

2

Description

Control group: will include non-opium user patients with a BMI less than 35. Who have consumed solid food in the last 8 hours or consumed clear liquids in the last 2 hours. And all the interventions performed for intervention group 1 will be performed in the control group.

Category

Treatment - Drugs

3

Description

Control group 2: will include non-opium user patients with a BMI less than 35. Have consumed solid food in the last 8 hours or consumed clear liquids in the last 2 hours. Have consumed solid food in the last 8 hours or consumed clear liquids in the last 2 hours. All interventions in this group will be similar to the intervention group, but instead of administering metoclopramide, 2 ml of distilled water will be injected intravenously (placebo) for these patients.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam hosein hospital

Full name of responsible person

Mohammad javad Yazdipoor

Street address

Madani St

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin zarghi

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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

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

5

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mohamad javad Yazdipoor

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Emergency Medicine

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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
Disagreement of some study participants with sharing of their 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