

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of plasil administration on criterias of gastric emptying according to sonography in urgent surgical patients with incomplete NPO time.

Protocol summary

Study aim

Effect of Plasil on Ultrasound Quantitative and Qualitative Criteria for Gastrointestinal Infarction in Patients with Incomplete Fasting Time

Design

Clinical trial with two groups: Plasma and placebo, parallel groups, double blind, randomization

Settings and conduct

Patients who have consumed solid food for fewer than 8 hours or consumed fluids in fewer than 2 hours and referred to Imam Hossein Hospital Operating Room or patients referred to Imam Hossein Hospital Emergency. After obtaining full consent and explanations on how the project will be implemented, enter the study. Patients were randomly assigned to receive either 10 mg (2 cc) or 2 cc distilled water based on a randomized number table and baseline values were recorded in all groups.

Participants/Inclusion and exclusion criteria

All patients who are admitted to the operating room of Imam Hussein Hospital emergency room have an NPO time of fewer than 8 hours for solids or less than 1 hour for clear fluids.

Intervention groups

Plasil group Placebo group

Main outcome variables

Gastric antral grade

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120430009593N12**

Registration date: **2020-02-17, 1398/11/28**

Registration timing: **retrospective**

Last update: **2020-02-17, 1398/11/28**

Update count: **0**

Registration date

2020-02-17, 1398/11/28

Registrant information

Name

Elham Memary

Name of organization / entity

Shahid Beheshti University

Country

Iran (Islamic Republic of)

Phone

+98 21 7755 8082

Email address

drmemory@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-22, 1398/04/01

Expected recruitment end date

2019-10-22, 1398/07/30

Actual recruitment start date

2019-06-22, 1398/04/01

Actual recruitment end date

2019-10-22, 1398/07/30

Trial completion date

2019-10-22, 1398/07/30

Scientific title

The effect of plasil administration on criterias of gastric emptying according to sonography in urgent surgical patients with incomplete NPO time.

Public title

Effect of plasil on criterias of gastric emptying

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All patients who are admitted to the operating room of Imam Hossein Hospital with an NPO time of fewer than 8 hours for solids or less than 1 hour for clear fluids Have enough time to do ultrasound and study Patient consent after explanation No contraindication for the administration of plasil The patient has the ability to position himself properly for the ultrasound The patient does not have gastrointestinal obstruction The patient has no history of gastric surgery Do not have hyaline rickets The patient has no history of diabetes BMI < 35 The patient has no reflux problem The patient should not be treated with stimulants or gastrointestinal drugs

Exclusion criteria:

After administration of plasil or placebo, the patient consumes food or water Vomiting after administration of plasil or placebo

Age

From **15 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

• Randomization method: Simple randomization • Randomization Unit: based on patient • Randomization Tool: Random Number Table - block stratified randomization software wnidow version 6.0 Using this software, a random number table is created and the sample list is divided into two groups of 30 each.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants entrance into the case and control groups on the basis of a randomized number table. They also provide a package containing 30 medications and 30 placebo for the doctor. The doctor prescribes the medication to patients Blindly.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

thics committee of Shahid Beheshti University of Medical Sciences

Street address

Velenjak Street, University Blvd

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2019-05-26, 1398/03/05

Ethics committee reference number

IR.SBMU.MSP.REC.1398.186

Health conditions studied

1

Description of health condition studied

Aspiration

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Gastric antral grade

Timepoint

Measurement of gastric antrum at baseline and 30 min after injection

Method of measurement

Ultrasound

Secondary outcomes

1

Description

Decrease in Aspiration Mortality

Timepoint

Gastric antrum measurement at baseline and 30 min after injection

Method of measurement

Ultrasound

Intervention groups

1

Description

As plasil accelerates gastric emptying, we used this drug, which is called metoclopramide, and was administered to patients with vial injection of 4 cc, equivalent to 1 mg in adults. It was administered 2 times and the ultrasound of patients was performed 2 times by radiologist and

assistant professor of Imam Hossein Hospital.

Category

Treatment - Drugs

2

Description

Control group: placebo

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Operating Room of Imam Hossein Hosp

Full name of responsible person

Dr Elham Memary

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Imam Hossien Hospital, Shahid Madani Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr 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

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Marzieh Rostami

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

dr Elham Memari

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data

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Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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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