

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

Compare the effect of topical heat therapy and room temperature on gastric residual volume and gastrointestinal tract function in patients being fed through nasogastric tube

Protocol summary

Summary

The purpose of this study is to compare the effect of topical heat therapy and room temperature on gastric residual volume and gastrointestinal tract function in patients being fed through nasogastric tube hospitalized in internal ward. Inclusion criteria are the existence of absolute diagnosis of any internal problems by the specialist physician. All of the patients will be gavaged with food prepared in the hospital, without any clinical situation, according to reliable sources and an expert therapist, with uncertainty or restriction of using topical heat therapy. Exclusion criteria: Discharge or death of patient, stopping gavage because of illness, conditions cause fever and temperature higher than 38 ° C. A total of fifty patients, aged 35- 100 years old, who are admitted in Ghaem Hospital due to any medical problem, will be randomly assigned into intervention or control group. The patients in the intervention group will receive standard hot pack with a temperature of 50 ° C placed for about 23 minutes on surface of the abdomen. The patients in the control group do not receive any intervention. Gastric residual volume, abdominal distension, bowel sounds, and defecation will be controlled before and after the test in both groups. At the end the results will be compared between two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015050822163N1**
Registration date: **2015-09-07, 1394/06/16**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-09-07, 1394/06/16

Registrant information

Name

Sadighe Sadeghian

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Gonabad University of Medical Sciences

Expected recruitment start date

2015-05-22, 1394/03/01

Expected recruitment end date

2015-10-23, 1394/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Compare the effect of topical heat therapy and room temperature on gastric residual volume and gastrointestinal tract function in patients being fed through nasogastric tube

Public title

The effect of topical heat therapy on function of the gastrointestinal tract

Purpose

Prevention

Inclusion/Exclusion criteria
 Inclusion criteria: Age between 35-100 years old, the existence of absolute internal diagnosis such as respiratory disorders by the specialist physician, having nasogastric tube number 16- 14, have been passed more than 48 hours from starting feeding through a gastric tube, nutrition with solution prepared in the hospital, patients with consciousness level higher than 9, having non-fasting blood sugar below 220 mg/dl, there is not also surgery last month, disorders such as pancreatic, peptic ulcer disease, a history of stomach bleeding.
 Exclusion criteria: Discharge or death of patient, stop gavage because of illness, conditions cause fever and temperature higher than 38 ° C.

Age
 From **35 years** old to **100 years** old

Gender
 Both

Phase
 N/A

Groups that have been masked
No information

Sample size
 Target sample size: **50**

Randomization (investigator's opinion)
 Randomized

Randomization description

Blinding (investigator's opinion)
 Single blinded

Blinding description

Placebo
 Not used

Assignment
 Parallel

Other design features
 Cases were randomly divided into the intervention and control groups. Study Type: single blind clinical trial. Researchers does not know the allocation of Patients to the control or the intervention group. Hot Pack's put on by research assistance; while researcher assesses the gastrointestinal tract function.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Gonabad University of Medical Sciences

Street address

Gonabad University of Medical Sciences, Next to the Asian Road, Gonabad, Iran

City

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Postal code

9691793718

Approval date

2015-03-11, 1393/12/20

Ethics committee reference number

GMU.REC.1393.144

Health conditions studied

1

Description of health condition studied

Respiratory diseases

ICD-10 code

J00-J06,J0

ICD-10 code description

Acute upper respiratory infections Influenza and pneumonia Other acute lower respiratory infections Other diseases of upper respiratory tract Chronic lower respiratory diseases Other diseases of pleura Other diseases of the respiratory system Pneumonia in

2

Description of health condition studied

Gastrointestinal disorders

ICD-10 code

K40-K46,K2

ICD-10 code description

Hernia Other diseases of the digestive system Disorders of oesophagus in diseases classified elsewhere Disorders of other digestive organs in diseases classified elsewhere

3

Description of health condition studied

Kidney disease

ICD-10 code

N17,N18,N1

ICD-10 code description

Acute renal failure Chronic kidney disease Unspecified kidney failure Essential (primary) hypertension Hypertensive heart disease Hypertensive renal disease Hypertensive heart and renal disease Secondary hypertension

4

Description of health condition studied

Infectious diseases

ICD-10 code

A04,A05,A0

ICD-10 code description

Other bacterial intestinal infections Other bacterial foodborne intoxications, not elsewhere classified Amoebiasis Other protozoal intestinal diseases Viral and other specified intestinal infections Other gastroenteritis and colitis of infectious and unsp

Primary outcomes

1

Description

Gastric residual volume
Timepoint
Every 3 hrs exactly before doing gavage
Method of measurement
By using 50cc gavage syringe

Secondary outcomes

1

Description
Bowel sound
Timepoint
Every 3 hrs exactly before doing gavage
Method of measurement
Stethoscope

2

Description
Defecation
Timepoint
Every 3 hrs exactly before doing gavage
Method of measurement
Observation

3

Description
Abdominal distension
Timepoint
Every 3 hrs exactly before doing gavage
Method of measurement
Physical examination

Intervention groups

1

Description
Intervention group: local heat therapy on the surface of the abdomen with Standard hot pack containing silicate with the temperature of 50°C for 23 min two times a day for 1 days.
Category
Prevention

2

Description
In Control group:without intervention
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Mashhad University of Medical Sciences, Ghaem Hospital.

Full name of responsible person
Dr.Maasomeh salari
Street address
Ghaem Hospital, Ahmad abad Street, Mashhad,Iran
City
Mashhad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Gonabad University of Medical Sciences
Full name of responsible person
Dr.Ali mohammad pour
Street address
Gonabad University of Medical Sciences, Next to the Asian Road, Gonabad, Iran
City
Gonabad
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, Gonabad 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
Gonabad University of Medical Sciences
Full name of responsible person
Sadighe sadeghian
Position
Master degree Students in Critical Care Nursing
Other areas of specialty/work
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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