

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

Compare the effect of early ambulation and gradually ambulation with exercise in bed on hemodynamic factors and complication of sleeve gastrectomy operation

Protocol summary

Summary

Objective: Compare the effect of early ambulation and gradually ambulation with exercise in bed on hemodynamic factors and complication of sleeve gastrectomy operation. Study population: patients undergoing sleeve gastrectomy, has a medical record in the Shiraz Ghadir Mother and child sub_specialized hospital. Inclusion and exclusion criteria: body mass index over 30 main criteria inclusion and main exclusion criteria complication during surgery. Sample size: 44 people early ambulation group (Group 1); 44 gradually ambulation with exercise in bed (Group 2); 44 patients in the control group (Group 3) were allocated. primary outcome variables: Pain, Vomiting, Arterial oxygen saturation ,Blood pressure

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016051527904N1**

Registration date: **2016-06-22, 1395/04/02**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-06-22, 1395/04/02

Registrant information

Name

Mohammad Reza Koohpeyma

Name of organization / entity

Yasuj

Country

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Yasuj University of Medical Sciences

Expected recruitment start date

2016-05-15, 1395/02/26

Expected recruitment end date

2016-08-16, 1395/05/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Compare the effect of early ambulation and gradually ambulation with exercise in bed on hemodynamic factors and complication of sleeve gastrectomy operation

Public title

Compare the effect of early ambulation and gradually ambulation with exercise in bed, on complication of operation

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Interested in participating in the study; Age between 18 and 55 years; Don't have history of respiratory disease; Don't have history of mental disorders; Don't use to addict to opioid and cigarettes; Have literacy; Body mass index was between $BMI \geq 30$, $BMI \leq 55$. Exclusion criteria: Discontinue to participate in the study; Musculoskeletal pain due to positioning during

surgery; Intolerance intervention protocol; Abnormal complication during surgery: including damage to blood vessels, removing excess stomach and ...; In the event that leaks occur after stomach surgery incision.

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **132**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Random allocation block

Secondary Ids

1

Registry name

-

Secondary trial Id

-

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Yasuj University of Medical Sciences

Street address

Iran, Yasuj, motahari martyr BLVD, Yasuj University of Medical Science, office of research and technology

City

Yasuj

Postal code

Approval date

2016-05-14, 1395/02/25

Ethics committee reference number

IR.YUMS.REC.1395.30

Health conditions studied

1

Description of health condition studied

sleeve gastrectomy

ICD-10 code

-

ICD-10 code description

-

Primary outcomes

1

Description

pain

Timepoint

Before the operation, after entrance to the ward , after the first intervention, 6 hours after the intervention , 12 hours after the intervention , 24 hours after intervention

Method of measurement

base on V.A.S scale

2

Description

vomiting

Timepoint

Before the operation, after entrance to the ward , after the first intervention, 6 hours after the intervention , 12 hours after the intervention , 24 hours after intervention

Method of measurement

Based on the frequency and patient interview

3

Description

oxygen saturation

Timepoint

Before the operation, after entrance to the ward , after the first intervention, 6 hours after the intervention , 12 hours after the intervention , 24 hours after intervention

Method of measurement

pulse oxymeter

4

Description

blood pressure

Timepoint

Before the operation, after entrance to the ward , after the first intervention, 6 hours after the intervention , 12 hours after the intervention , 24 hours after intervention

Method of measurement

blood pressure monitor

Secondary outcomes

empty

Intervention groups

1

Description

early ambulation

Category

Rehabilitation

2

Description

intervention group 2: gradually ambulation with exercise in bed

Category

Rehabilitation

3

Description

control group: Out of bed based on routine in ward

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Shiraz University of Medical Sciences

Full name of responsible person

Mohammad Reza Koohepeyma

Street address

Shiraz-ghadir Mother and child subspecialized hospital

City

shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Office of research of Yasuj University of Medical Science

Full name of responsible person

Dr. Akbartabar mehdi

Street address

Iran, Yasuj, motahari martyr BLVD, Yasuj University of Medical Science, office of research of Yasuj University of Medical Science

City

Yasuj

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Office of research of Yasuj University of Medical Science

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

Yasuj University of Medical Science

Full name of responsible person

Sayed Javad sadat

Position

MSc medical surgical nursing

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