Clinical Trial Protocol
Iranian Registry of Clinical Trials
27 Apr 2020

Effect of early ambulation after surgery on nausea and vomiting in patients undergoing appendectomy

Protocol summary

Summary
In this clinical trial, 60 candidates for Appendectomy Procedure who are admitted in Mashhad hospital’s (Emam Reza and doctor shykh) in 2013, will randomly allocated into two early ambulation and control group. In intervention group, 4 hours after surgery when patients awake, they leave the bed in four stage and walk around the bed and in the corridor. In any stage, the vital signs are measured (4, 6, 8 and 10 hours after surgery) and severity nausea and vomiting scale and nausea duration scale will use for evaluating the nausea and vomiting. Conventional care is done in control group and they leave the bed after physician order. Data will analyzed by using 16 spss software.

General information

Acronym
IRCT registration information
IRCT registration number: IRCT2013012312245N1
Registration date: 2013-02-25, 1391/12/07
Registration timing: registered_while_recruiting

Last update: empty
Update count: 0
Registration date: 2013-02-25, 1391/12/07

Registrant information
Name
Hamid Ebrahimi
Name of organization / entity
Mashhad University of Medical Science
Country
Iran (Islamic Republic of)
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+98 51 1859 1511
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ebrahimi5@mums.ac.ir

Recruitment status
Recruitment complete
Funding source
Mashhad University of Medical Science

Expected recruitment start date
2013-01-30, 1391/11/11
Expected recruitment end date
2013-03-19, 1391/12/29
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of early ambulation after surgery on nausea and vomiting in patients undergoing appendectomy

Public title
Effect of early ambulation after surgery on nausea and vomiting in patients undergoing appendectomy

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria: Diagnosing Appendicitis and confirmation by physician and having an appendectomy surgery; Having age between 10 to 50 years at study; Patient consent to participate; Patients have the ability to speak Persian; All patients were alert enough to determine the severity of nausea and vomiting.
Exclusion criteria: Patients in the intervention group had lower limb movement disorder or malfunction; Patients with drug addiction; Patients with chronic diseases such as gastrointestinal disorders, cancer, heart disease, respiratory problems, inner ear; Surgery other than appendectomy; Appendectomy with laparoscopic surgery; use anti emetic agents to reduce nausea and vomiting; Patient reluctance; Patients with peritonitis

Age
From 10 years old to 50 years old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size:

Randomization (investigator’s opinion)
Randomized

Randomization description
Blinding (investigator's opinion)
Not blinded

Blinding description
Placebo
Not used

Assignment
Parallel

Other design features

Secondary IDs
empty

Ethics committees

1
Ethics committee
Name of ethics committee
Mashhad University of Medical Science
Street address
doctora Crossroad
City
Mashhad
Postal code
00985118591511
Approval date
2012-10-21, 1391/07/30
Ethics committee reference number
511/2802

Health conditions studied

1
Description of health condition studied
Appendicitis
ICD-10 code
k35-8
ICD-10 code description
Acute appendicitis without mention of localized or
generalized peritonitis

Primary outcomes

1
Description
Nausea and Vomiting
Timepoint
10 hours after surgery
Method of measurement
visual analoug scale of nausea severity and Four
Multimode scale of vomiting

Secondary outcomes
empty

Intervention groups

1
Description
in the test group: early ambulation in four stage after
surgery(4, 6, 8, 10 hours) after transferring patients to
surgery ward.
Category
Prevention

2
Description
In control group: Conventional care is performed (no
action)
Category
Prevention

Recruitment centers

1
Recruitment center
Name of recruitment center
Mashhad University of Medical Science (Faculty of
Nursing and Midwifery)-Emam Reza and Doctor
Shiykh
Full name of responsible person
Hamid Ebrahimi
Street address
Doctora Crossroads
City
Mashhad

Sponsors / Funding sources

1
Sponsor
Name of organization / entity
Mashhad University of Medical Science
Full name of responsible person
Mohammad Ramezani (Ph.D., Pharm.D.)
Street address
University Ave.
City
Mashhad
Grant name
Grant code / Reference number
Is the source of funding the same sponsor
organization/entity?
Yes
Title of funding source
Mashhad 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
Person responsible for general inquiries

Contact
Name of organization / entity
Faculty of Nursing and Midwifery of Mashhad
Full name of responsible person
Hamid Ebrahimi
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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