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

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)
**Randomization description**
- Not blinded

**Blinding (investigator's opinion)**
- Not blinded

**Blinding description**
- Placebo
  - Not used

**Assignment**
- Parallel

**Other design features**
- Secondary Ids
  - empty

**Ethics committees**

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

**Health conditions studied**

<table>
<thead>
<tr>
<th>Description of health condition studied</th>
<th>ICD-10 code</th>
<th>ICD-10 code description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appendicitis</td>
<td>k35-8</td>
<td>Acute appendicitis without mention of localized or generalized peritonitis</td>
</tr>
</tbody>
</table>

**Primary outcomes**

<table>
<thead>
<tr>
<th>Description</th>
<th>Timepoint</th>
<th>Method of measurement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nausea and Vomiting</td>
<td>10 hours after surgery</td>
<td>visual analog scal of nausea severity and Four Multimode scal of vomiting</td>
</tr>
</tbody>
</table>

**Secondary outcomes**
- empty

**Intervention groups**

<table>
<thead>
<tr>
<th>Description</th>
<th>Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>in the test group: early ambulation in four stage after surgery(4, 6, 8, 10 hours) after transferring patients to surgery ward.</td>
<td>Prevention</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Description</th>
<th>Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>In control group: Conventional care is performed (no action)</td>
<td>Prevention</td>
</tr>
</tbody>
</table>

**Recruitment centers**

<table>
<thead>
<tr>
<th>Recruitment center</th>
<th>Name of recruitment center</th>
<th>Street address</th>
<th>City</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Mashhad University of Medical Science (Faculty of Nursing and Midwifery)-Emam Reza and Doctor Shiykh</td>
<td>Doctora Crossroads</td>
<td>Mashhad</td>
</tr>
</tbody>
</table>

**Sponsors / Funding sources**

<table>
<thead>
<tr>
<th>Sponsor</th>
<th>Name of organization / entity</th>
<th>Full name of responsible person</th>
<th>Street address</th>
<th>City</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Mashhad University of Medical Science</td>
<td>Mohammad Ramezani (Ph.D., Pharm.D.)</td>
<td>University Ave.</td>
<td>Mashhad</td>
</tr>
</tbody>
</table>

**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
Position
Nursind Student(Msc)
Other areas of specialty/work
Street address
Mashhad University of Medical Science
City
Mashhad
Postal code

Phone
+98 51 1859 1511
Fax
Email
ebrahimih5@mums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Faculty of Nursing and Midwifery of Mashhad
Full name of responsible person
Fatemeh Asadi
Position
Msc of Nursing
Other areas of specialty/work
Street address
Mashhad University of Medical Science
City
Mashhad
Postal code

Phone
+98 51 1859 1511
Fax
Email
asadif@mums.ac.ir
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