A survey effect of patients early mobilization program on the Physical and mental conditions of patients with MI hospitalized in CCU

Protocol summary

Summary
Title: A survey effect of patients early mobilization program on the Physical and mental conditions of patients with MI hospitalized in CCU. Introduction: One of the recommended treatments for patients with MI are resting in bed, but prolonged bed rest has many complications. Nowadays early mobilization of patients with MI hospitalized in CCU has been considered, but there is no specific instruction for early mobilization of patients with MI hospitalized in CCU. This study is performed to determine effect of patients early mobilization program on the Physical and mental conditions of patients with MI hospitalized in CCU. Method: 40 patients with MI hospitalized in CCU is selected by the method of Purposive sampling and then they are randomly allocated in two groups of test and control. Test group start activity within 12-18 hours after admission on according to a specified and controlled program. Control group start activity 48 hours after admission on according to routine method. Then some physical and psychological status parameters after MI in the two groups are evaluated and compared. Method of data collection is by questionnaires, check list, and related tools.

General information
Acronym
IRCT registration information
IRCT registration number: IRCT201201138717N1
Registration date: 2012-01-26, 1390/11/06
Registration timing: prospective

Registrant information
Name
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Recruitment status
Recruitment complete
Funding source
Semnan University of Medical Sciences

Expected recruitment start date
2012-02-04, 1390/11/15
Expected recruitment end date
2012-10-06, 1391/07/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
A survey effect of patients early mobilization program on the Physical and mental conditions of patients with MI hospitalized in CCU

Public title
The effect of patients early mobilization program on the Physical and mental conditions of patients with MI

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria: (1) age of participants less than 70 years, (2) lack of hemodynamic dysfunction (systolic
blood pressure Under 100 mmHg and more than 180 mmHg), absence of arrhythmias, and absence of shortness of breath or chest pain before the start of each stage, (3) lack of atrial ventricular block grade two and three, (4) lack of cardiac complications which is confirmed by a cardiologist after echocardiography, (5) lack of acute psychiatric disorders, (6) lack of motor disorders. Exclusion criterias: (1) Patients addicted to narcotic substances, (2) Patients who have a history of cardiopulmonary resuscitation, (3) Patients with myocardial infarction complicated by [hemodynamic disorder, congestive heart failure, signs of carcinogenic shock, continuity of atrial and ventricular arrhythmias, existence of atrial ventricular block grade two and three, pericarditis, pulmonary embolism, stroke or transient ischemic attack, stroke], (4) Patients during stages of the walk have intolerance procedure for three times consecutive, (5) Unwillingness of patients to perform the early mobilization program, (6) Patients who undergoing percutaneous coronary intervention [PCI] and (7) Patients who are treated with thrombolytictherapy.

<table>
<thead>
<tr>
<th>Age</th>
<th>From 30 years old to 70 years old</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td>Both</td>
</tr>
</tbody>
</table>

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: 40

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Blinding (investigator's opinion)

Single blinded

**Blinding description**

Placebo

Not used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee**

Name of ethics committee

Semnan University of Medical Sciences

Street address

Semnan University of Medical Sciences, Semnan, Iran

City

Semnan

Postal code

3519819973

Approval date

2012-01-16, 1390/10/26

**Ethics committee reference number**

136462/90

**Health conditions studied**

1

**Description of health condition studied**

Acute myocardial infarction

**ICD-10 code**

I21

**ICD-10 code description**

Acute myocardial infarction

**Primary outcomes**

1

**Description**

Hear Rate

**Timepoint**

Every 6 hours

**Method of measurement**

To view the monitor screen

2

**Description**

Blood pressure

**Timepoint**

Every 6 hours

**Method of measurement**

According to mmHg by the Pointer manometer

3

**Description**

Ejection fraction

**Timepoint**

18-12 and 72 hours after MI

**Method of measurement**

Echocardiography machine

4

**Description**

Anxiety

**Timepoint**

In the first 12-18 and 72 hours after admission

**Method of measurement**

By Hospital Anxiety and Depression Scale (HADS)

5

**Description**

Depression

**Timepoint**

In the first 12-18 and 72 hours after admission

**Method of measurement**

By Hospital Anxiety and Depression Scale (HADS)
<table>
<thead>
<tr>
<th>Description</th>
<th>Timepoint</th>
<th>Method of measurement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duration of stay in hospital</td>
<td>Time of discharge</td>
<td>According to hours</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Description</th>
<th>Timepoint</th>
<th>Method of measurement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frequency of pain</td>
<td>After 72 hours</td>
<td>Looking at records</td>
</tr>
</tbody>
</table>

**Secondary outcomes**
empty

**Intervention groups**

1. **Description**
   A) Intervention group: the first day, the first stage: In this stage, patients 12-18 hours after admission in hospital, setting from prone position to sitting position and after checking blood pressure and heart rate and lack of hemodynamic disorder and arrhythmia, with direct supervision of researcher, his legs hung bedside for 5 minutes, then return to prone position again. The second stage: at least three hours after the first stage and resting in bed, after checking blood pressure and heart rate and lack of hemodynamic disorder and arrhythmia or incidence of pain, under direct supervision of researcher, after hanging legs and lack of incidence of hemodynamic problems, arrhythmia or pain, patient comes down from the bed and sits on the chair in bedside for five minutes and then return to bed and rest. The second day, the third stage: 24 hours after admission patient, after checking blood pressure, heart rate, lack of hemodynamic disorder and arrhythmia, lack of chest pain and dyspnea, under direct supervision of researcher, patient sits on the chair in bedside for ten minutes and then return to self bed. The fourth stage: at least three hours after the third stage, under direct supervision of researcher, If there is no problem (pain, arrhythmia, hypotension, unwillingness of patients), patient standing and walking in bedside for ten minutes and then return to self bed. The fifth stage: at least three hours after the fourth stage, under direct supervision of researcher, first patient walks in bedside for five minutes and then walks in CCU in the limit of tolerance (range of ten steps to go and ten steps to back) for five minutes and then return to self bed. The sixth stage: 48 hours after admission, if the patient is no problem, under direct supervision of researcher, first patient walks in bedside for five minutes and then if there is no problem (pain, arrhythmia, hypotension, unwillingness of patients), walks in CCU in the limit of tolerance (range of ten steps to go and ten steps to back) for ten minutes and then return to self bed. The seventh stage: at least three hours after the sixth stage, under direct supervision of researcher, if there is no problem (pain, arrhythmia, hypotension, unwillingness of patients), walks in CCU in the limit of tolerance (range of twenty steps to go and twenty steps to back) for fifteen minutes and then return to self bed. The eighth stage: at least three hours after the previous step, this step is repeated as the seventh stage and if there is no problem, patient is in the state of relative rest.

2. **Description**
   B) control group According to the ward routine, 48 hours after admission, patients are ambulated with the help and supervision of researcher.

**Recruitment centers**

1. **Recruitment center**
   **Name of recruitment center**
   CCU of Babol Shahid Beheshti hospital
   **Full name of responsible person**
   Hasan Ali Jafarpour
   **Street address**
   Iran - Mazandaran - Babel - keshvari Square - Shahid Beheshti hospital - CCU
   **City**
   Babol

**Sponsors / Funding sources**

1. **Sponsor**
   **Name of organization / entity**
   Semnan University of Medical Sciences, Semnan, Iran
   **Full name of responsible person**
   Dr. Raheb Ghorbani
   **Street address**
   Research and Technology Deputy of Semnan University of Medical Sciences, Basij Boulevard, Semnan, Iran
   **City**
   Semnan
   **Grant name**
   اعیانات پژوهشی دانشگاه علوم پزشکی
   **Grant code / Reference number**
   Is the source of funding the same sponsor organization/entity?
   Yes
Title of funding source
Semnan University of Medical Sciences, Semnan, Iran
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
empty
Type of organization providing the funding
empty

Person responsible for general inquiries
Contact
Name of organization / entity
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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