

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 2026

The effect of comprehensive caring program on health outcomes of patients with general abdominal surgery in Zanjan.1389

Protocol summary

Summary

In this clinical trial, 118 patients (15-65 years) without chronic and disabling diseases that undergoing abdominal surgery in Zanjan Mousavi hospital will be randomly assigned in two groups. During hospitalization, the control group (59 cases) will receive routine program care and intervention group (59 cases), Will receive a plan of care including: physical, psychological and educational care. Intervention time is preoperative education for patients, 4-6 hours after surgery and the second morning after surgery on nursing process and time of hospital discharge, by education booklet. The health outcome of patients, including: pain, anxiety, nurse – patient communication, satisfaction, non-routine visit after discharge, and postoperative complications is one week after discharge will be evaluated .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201103105987N3**

Registration date: **2011-06-18, 1390/03/28**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-06-18, 1390/03/28

Registrant information

Name

Shahrzad Ghiyasvandian

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6692 7171

Email address

shghiyas@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

research deputy and educational of tehran university
medical science

Expected recruitment start date

2010-09-23, 1389/07/01

Expected recruitment end date

2011-01-20, 1389/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of comprehensive caring program on health outcomes of patients with general abdominal surgery in Zanjan.1389

Public title

The effect of comprehensive caring program on health outcomes

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: All patients that hospitalization at least 4 hours before abdominal surgery in emergency or surgery ward; age between 15 to 65 years old; absence of chronic and disabling diseases; not have been immune deficient and case for cancer or use of immunosuppressive drugs and $18.5 < \text{BMI} < 30$ Exclusion criteria: Patient who dies or refers to ICU; re-admission due to surgical techniques complications and hospitalization more than 10 days and less than 48 hours

Age

From **15 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **118**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Use of Watson theory

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

ethics committee of tehran university medical science

Street address

6th floor, university of central organization, Ghods Ave, St Bolvar Keshavarze

City

tehran

Postal code

Approval date

2010-07-06, 1389/04/15

Ethics committee reference number

89130/805ص

Health conditions studied

1

Description of health condition studied

General abdominal surgery

ICD-10 code

Z09.0

ICD-10 code description

Follow-up examination after surgery for other conditions

Primary outcomes

1

Description

Pain

Timepoint

6-4 hours after surgery, discharge day and 1 week after discharge

Method of measurement

Visual Analogue Scale

2

Description

Anxiety

Timepoint

Before intervention and on discharge day and 1 week after discharge

Method of measurement

VAS(visual analogue scale)

3

Description

Satisfaction

Timepoint

1 week after discharge

Method of measurement

Self- made questionnaire

Secondary outcomes

1

Description

Complication after surgery

Timepoint

1 week after surgery

Method of measurement

Study check list

2

Description

Unplanned medical visits

Timepoint

1 week after surgery

Method of measurement

questionnaire

Intervention groups

1

Description

Intervention group: receives comprehensive caring program consist spiritual, mental and educational care and information booklet at discharge day

Category

Other

2

Description

Control group: receives standard hospital care

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Mousavi Hospital, Surgery ward

Full name of responsible person

Liela Alizadeh, nursing graduate student

Street address

Mousavi Hospital, Gavazang way

City

Zanjan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tehran University of Medical Sciences

Full name of responsible person

Masod Yonesian

Street address

6th floor, Central Building, Ghods Ave., Keshavarz Boulevard

City

Tehran

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, Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Shahzad Ghiyasvandian

Position

Ph.D

Other areas of specialty/work**Street address**

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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