

# 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**

Faculty of nursing & midwifery ,Tohid Square

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

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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*