

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of family caregiver-oriented discharge planning program on nutritional status, laboratory nutritional parameters and quality of life in patient suffering from hip fractures

Protocol summary

Summary

This study is a clinical trial includes two groups in order to defining the effect of family caregiver-oriented discharge planning program on nutritional status, laboratory nutritional parameters and quality of life in patient suffering from hip fractures. The study population includes All patients with the diagnosing of intertrochanteric hip fracture hospitalized in an orthopedic departments of Imam Khomeini hospital in Tehran with their family caregivers. Inclusion criteria: age of 18 years or older; hip fracture detection of intertrochanter, discharge to home (specific to nursing homes or care centers ... not reference); having at least one caregiver (the patient does not live alone it has to be watched). Exclusion criteria: multiple fractures or other pathological malignant and malignant diseases; irreversible phase of illness; seeking discharge against medical advice; create any type of trauma and serious illness after discharge to 6 months. Allocating patients in the two groups will done randomly on the basis of six blocks. According to volume formula, the number of samples needed in each group is 42 persons and 84 patients will determine totally. All participants signed an informed consent. Before intervention demographic questionnaire, nutritional status questionnaire (MNA), measuring laboratory nutritional parameters (albumin, total protein and TLC) as well as quality of life questionnaire (EQ-5D-5L) will be completed in both groups. control groups will receive the routine care by hospital personnel, but the intervention group will receive the family caregiver-oriented discharge planning. The discharge planning will start from hospitalization and will continue for 6 month after discharging. 6 weeks after discharge laboratory nutritional parameters, 3 months and 6 months after discharge and nutritional status and laboratory nutritional parameters and quality of life of these patients are re-evaluated. Also, six months after

discharge, mortality, readmission and fall will be measured in two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016072119141N2**

Registration date: **2016-09-30, 1395/07/09**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-09-30, 1395/07/09

Registrant information

Name

Hooman Shahsavari

Name of organization / entity

The faculty of Nursing and Midwifery of Tehran
University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6105 4319

Email address

h_shahsavari@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2016-09-22, 1395/07/01

Expected recruitment end date

2018-02-20, 1396/12/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of family caregiver-oriented discharge planning program on nutritional status, laboratory nutritional parameters and quality of life in patient suffering from hip fractures

Public title
The effect of family caregiver-oriented discharge planning program on nutritional status, laboratory nutritional parameters and quality of life in patient suffering from hip fractures

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria: age 18 years or older; hip fracture detection of intertrochanter, discharge to home (specific to nursing homes or care centers ... not reference); having at least one caregiver (the patient does not live alone it has to be watched). Exclusion criteria: multiple fractures or other pathological malignant and malignant diseases; irreversible phase of illness; seeking discharge against medical advice; create any type of trauma and serious illness after discharge to 6 months

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **84**

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

Ethicsl Committee of Tehran Faculty of Nursing and

Midwifery and rehabilitation

Street address
Faculty of Nursing and Midwifery, Nosrat Sharghi Street, Tohid Square, Tehran Tehran

City
Tehran

Postal code

Approval date
2016-08-31, 1395/06/10

Ethics committee reference number
IR.TUMS.FNM.REC.1395.531

Health conditions studied

1

Description of health condition studied

Hip fracture

ICD-10 code

S72.1

ICD-10 code description

Pertrochanteric fracture

Primary outcomes

1

Description

Nutritional status

Timepoint

Before intervention, 3 and 6 months after intervention

Method of measurement

minin Nutritional Assessment Questionnaire (MNA)

2

Description

Laboratory Nutritional Parameters (albomin,total protein,total lymphocyte counts)

Timepoint

Before intervention, 3 and 6 months after intervention

Method of measurement

Lab sampling

3

Description

Quality of life

Timepoint

Before intervention, 3 and 6 months after intervention

Method of measurement

Quality of life questionnaire (EQ-5D-5L)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: the discharge planning will start from the time of patient hospitalization and continue for 6 months after discharging. The stages of performing discharge planning are: This group will receive a training booklet includes training fractures, symptoms, complications and treatment, limitation of activity, education, exercise programs, adaptive techniques to perform daily activities, nutritional advice, use of mobility aids, self care, care wounds, medications, complications, health care follow-up time in addition to the individual face to face training in the postoperative period during the three sessions, each session lasting 1 hour based on patient preference in terms of timing. The researcher will call each of the patients once two weeks for 6 months after discharging to problems raised and check the patient improved, reaching to the aims and adherence the trail planning. The researchers throughout the week by the phone is available for patients and family caregivers. During the phone calls necessary arrangements to meet with the patient in the clinic 6 weeks, 3 months and 6 months after discharge will be told.

Category
Other

2

Description

Control group: patients in the control group will receive the same routine training from nurses in Orthopedic units.

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Sahar malehmir

Street address

Imam Khomeini Hospital, Keshavarz Blvd., Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Masood Younesian

Street address

Central building of Tehran University of Medical Sciences, Qhds street, Keshavarz Blvd.

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

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

Faculty of Nursing and Midwifery, Tehran University of Medical Sciences

Full name of responsible person

Sahar Malehmir

Position

Master of Nursing

Other areas of specialty/work

Street address

Faculty of Nursing and Midwifery, Nosrat Sharghi Street, Tohid Square, Tehran

City

Tehran

Postal code

Phone

+98 216633309193

Fax

Email

saharmalmir93@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Faculty of Nursing and Midwifery, Tehran University of Medical Sciences

Full name of responsible person

Dr. Hooman Shahsavari

Position

Assistant Professor

Other areas of specialty/work

Street address

Faculty of Nursing and Midwifery, Nosrat Sharghi Street, Tohid Square

City

Tehran

Postal code

Phone

+98 21 6693 7120

Fax

Email

h_shahsavari@sina.tums.ac.ir

Web page address

Phone

+98 21 6633 3091

Fax

Email

saharmalmir93@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Faculty of Nursing and Midwifery, Tehran University of
Medical Sciences

Full name of responsible person

Sahar Malehmir

Position

Master of Nursing

Other areas of specialty/work

Street address

Faculty of Nursing and Midwifery, Nosrat Sharghi
Street, Tohid square

City

Tehran

Postal code

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