

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

Clinical trial Comparing the effectiveness of educational- supportive program on quality of life and transplant acute complications in two groups of kidney transplant patients.

Protocol summary

Summary

This study is done to the investigate effect of educational supportive package on quality of life and transplant acute complications in kidney transplant patients. This study is quasi-experimental, non-randomized, available sample method, sample volume 72 person(each group 36 person). Patients with age of 18 to 60 years and ability of read and write can participate in study and they are omitted from the study upon appearance of transplant acute complications and prolonged hospitalization. By drawing lots between the two hospitals where the research is conducted, one place is allocated to test group and other to control group. On reaching the semi- study, for create equal conditions, groups study place is replaced. By obtaining a written consent indicating voluntary participation and prior to commencement of intervention, demographic and disease questionnaire and kidney transplant specific questionnaire is completed by two groups. Educational supportive package contains 5 educational meetings 20 to 30 minutes based on care issues, stress decrease methods and matching with conditions, after relative recovery and during hospitalization period is conducted by the researcher through face to face method. The guidebook and 5 to 10 minute telephone contacts for responding to the patient's questions are included in this program. Control group receives routine training and cares of the ward. 8 weeks after the commencement of intervention, the quality of life specific questionnaire is completed by the patient and researcher made checklist for transplant acute complications is completed by the researcher in two groups and then, they are compared by using statistical methods.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201607254443N21**

Registration date: **2017-06-21, 1396/03/31**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-06-21, 1396/03/31

Registrant information

Name

Masoumeh Zakerimoghadam

Name of organization / entity

Tehran University of Medical Sciences

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Iran (Islamic Republic of)

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Email address

zakerimo@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Tehran university of medical sciences

Expected recruitment start date

2016-08-22, 1395/06/01

Expected recruitment end date

2016-11-21, 1395/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial Comparing the effectiveness of educational-supportive program on quality of life and transplant acute complications in two groups of kidney transplant patients.

Public title

Effect of education and supportive on quality of life and transplant acute complications in kidney transplant patients.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: age 18-60 year; least ability to read and write; interest to participate in study; the first transplant is done in patient; the patient is not member of treatment team; no history of mental disease.

Exclusion criteria: hyper acute transplant complications; staying over 20 days in hospital.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran university of medical sciences

Street address

Ghods street, Keshvarz boulevard

City

Tehran

Postal code

Approval date

2016-06-26, 1395/04/06

Ethics committee reference number

IR-TUMS-VCR- REC-1395-189: Ethics committee of Tehran university of medical sciences

Health conditions studied

1

Description of health condition studied

KIDNEY TRANSPLANT

ICD-10 code

Z94.0

ICD-10 code description

Kidney transplant status

Primary outcomes

1

Description

Quality of life

Timepoint

Before and 8 weeks after intervention start

Method of measurement

Quality of Life specific questionnaire in kidney transplant patients(KTQ-25)

Secondary outcomes

1

Description

Kidney transplant acute complications

Timepoint

8 weeks after intervention start

Method of measurement

Kidney transplant acute complications check list

Intervention groups

1

Description

In test group, interventions are as follows: face to face educational meetings is in five times 20 to 30 minutes. In this meetings is discussed on the patient's condition and the chronic nature of disease. Need to permanent care and follow-up, medicinal regime and diet importance in maintaining health and survival of transplanted kidney, understanding the risks and symptoms of rejection, new style of life and how to deal with common issues is discussed. Express fears and worry and respond to their questions take place in this meetings. Stress decrease methods such as listening to favorite music, thinking distraction by using favorite pastime and draw attention to issues other than illness, relaxation and relax the muscles and chants calming and all matching methods with this conditions is in educational supportive program. The guidebook which contains the necessary care points is given to the patients upon discharge and 5 to 10 minute telephone contacts are included in this program on a weekly basis during 8 weeks(by emphasizing the necessary care points and responding to the patient's questions).

Category

Other

2

Description

In control group no intervention is conducted by researcher and patients receive routine training and cares of the ward.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imamkhomeini hospital, Kidney transplant ward

Full name of responsible person

Zakerimoghadam Masoumeh

Street address

Eastern Nosrat street, Tohid square

City

Tehran

2

Recruitment center

Name of recruitment center

Shariati hospital- Kidney transplant ward

Full name of responsible person

Zakerimoghadam masoumeh

Street address

Eastern Nosrat street, Tohid square

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Tehran university of medical sciences

Full name of responsible person

Zakerimoghadam Masoumeh

Street address

Eastern Nosrat street, Tohid square

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 of 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

Nursing midwifery faculty of Tehran university of medical sciences

Full name of responsible person

Zakerimoghadam Masoumeh

Position

Nursing education PHD, Faculty member

Other areas of specialty/work

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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