

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

The impact of transitional care upon the rate of readmission in patients after Coronary Artery Bypass Graft

Protocol summary

Study aim

To determine the impact of transitional care upon the rate of readmission in patients after Coronary Artery Bypass Graft

Design

Randomized control trial containing two groups of 40 people (intervention and control)

Settings and conduct

Samples are selected in ICU-OH wards. During first week after discharge, in intervention group, each night, patient completes a checklist and sends its picture via internet messenger. In case of a new problem or any need to further explanation patient can call researcher. On the other hand, researcher calls patient in case of suspicious conditions to give some advice. In serious cases, researcher recommends patient to return the initial or nearest hospital. Researcher does two sessions of home visit ; first session in first week after discharge and the second one two weeks after that. The patient will be assessed according to the assessment form each session. In addition, researcher observes implementing instructions by patient and recommends referral to surgeon or other specialists if needed. Ultimately, readmission rate and other complications are compared between groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria consists of: Being in high risk group according to '30-days readmission score', living in Tehran/suburbs in first month after discharge, Having and being able to use mobile and internet messaging(patient/ his or her care giver), Not having vital organ complicated diseases and not having mental disease. Exclusion criteria consists of unwillingness to continue participating in research, Leaving Tehran/suburbs in first month after surgery, Hospital stay more than 10 days after surgery and patients death.

Intervention groups

Intervention group receive transitional care after discharge. though, control group receive only usual cares

of hospital discharge program.

Main outcome variables

Readmission rate, complications of surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180408039238N1**

Registration date: **2018-09-10, 1397/06/19**

Registration timing: **retrospective**

Last update: **2018-09-10, 1397/06/19**

Update count: **0**

Registration date

2018-09-10, 1397/06/19

Registrant information

Name

mehrnaz khishvand

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 26 3656 4998

Email address

m-khishvand@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-22, 1397/03/01

Expected recruitment end date

2018-08-23, 1397/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty
Trial completion date

empty

Scientific title

The impact of transitional care upon the rate of readmission in patients after Coronary Artery Bypass Graft

Public title

The impact of transitional care upon the rate of readmission in patients after Coronary Artery Bypass Graft

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Being in high risk group according to "30-days readmission score", containing: Diabetes mellitus, haematocrit less than 35 before surgery, Using On-pump technique for surgery, Serum glycemc index of 200 and more. Habitation in Tehran our suburbs in first month after discharge to ease the access to patients for home visits. Having access to a mobile phone and being able to use mobile and using telegram(patient or his or her home care person) for educational relation and tele-Health Not having vital organs complicated diseases(motor disfunction, rhumatoid artheritis, CVA,...) Not having mental diseases(Schizophrenia. psychosis, major depression,...)

Exclusion criteria:

Unwillingness of patient to continue participating in research . Leaving Tehran and suburbs in less than one month after discharge; because this impedes home visits. Hospital stay more than 10 days after CABG surgery leads to omitting the patient from samples. Patients death during first month after surgery.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Random blocking

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

Ethics committee of faculty of Nursing and Midwifery of Tehran University of Medical Sciences

Street address

Faculty of Nursing and Midwifery , Dr. Mirkhani St (Nosrat St) ,Towhid sq,Tehran

City

Tehran

Province

Tehran

Postal code

1419733171

Approval date

2018-01-31, 1396/11/11

Ethics committee reference number

IR.TUMS.FNM.REC.1396.4398

Health conditions studied

1

Description of health condition studied

Coronary Artery Bypass Graft Surgery

ICD-10 code

T82.9

ICD-10 code description

Unspecified complication of cardiac and vascular prosthetic device, implant and graft

Primary outcomes

1

Description

Readmission rate after discharge from hospital following Coronary artery bypass graft surgery

Timepoint

At the end of 30th day after discharge from hospital, readmission rate in groups (intervention and control) is measured.

Method of measurement

Asking patient and studying patient's case

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In intervention group, patient or

his/her home caregiver is trained by researcher about how to keep connection with researcher from home and help tele-nursing. Instructions consists of how to measure body temperature, pulse rate, respiratory rate, blood pressure, efficient using of incentive spirometry, stair workout, walking, appropriate position (sleeping, sitting and during activities), using medications, assessing and caring sternal or limb incision, measuring weight, warning signs and what to do if those occur, wearing sternal support, suitable diet precautions when taking a bath, praying and during travel. Patient/ home caregiver sends to researcher ,by internet messaging, a report from patient's condition(using the report form designed by researcher) each night in first week after discharge. It is said to patient that she/he can contact researcher by phone call or voice message in case of a new problem or needing to ask question. In case of not sending reports regularly, researcher reminds patient/caregiver by phone call. Researcher contacts patient/home caregiver in case of suspicious conditions and gives some advice or in serious cases recommends patient to return to the initial hospital or first hospital near his/her home. . Researcher does two sessions of home visit ;one in first week after discharge and second session two weeks after first session. In each session, general assessment of patient's state is done, researcher observes implementing instructions by patient and recommends referral to surgeon or other specialists if needed. Patient is recommended to return initial hospital or other hospital in case of occurrence of warning signs between home visit sessions and every other time needed.

Category

Prevention

2

Description

Control group: This group will receive routine care in hospital and after discharge follow ups. Ultimately, researcher will measure 30 day readmission rate in this group and will compare two groups.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati Hospital

Full name of responsible person

Saeed Reza Mehrpour

Street address

Shariati Hospital, On the corner of Jalal Al Ahmad and Kargar st, Tehran

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Tehran

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1411713135

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shariatihosp@tums.ac.ir

2

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Khosro Sadegh Neiat

Street address

Imam Khomeini Hospital, Gharib st, At the end of Keshavarz blvd, Tehran

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Email

Imamhospital@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Faculty of nursing and midwifery of Tehran university of medical sciences

Full name of responsible person

Alireza Nikbakht Nasr Abadi

Street address

Room 48, Tehran School of Nursing & Midwifery, Tohid Sq.,Tehran, Iran.

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Email

Nikbakht@tums.ac.ir

Grant name

Not determined yet

Grant code / Reference number

هنوز مشخص نیست

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

Yes

Title of funding source

Faculty of nursing and midwifery of Tehran university of medical sciences

Proportion provided by this source

50

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Mehrnaz Khishvand

Position

Nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

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Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

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Position

Student of Master of Science

Latest degree

Bachelor

Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

we have not decided about this topic yet.

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

If we decided to share data file, it will be done unanimously both for demographic data and main outcome.

When the data will become available and for how long

It will be available from 2019

To whom data/document is available

Just will be available for academic staff.

Under which criteria data/document could be used

For secondary analysis, conducting comparative studies or met-analysis.

From where data/document is obtainable

They should send request for access to data to this Email
Address: M-khishvand@razi.tums.ac.ir

What processes are involved for a request to access**data/document**

In case of eligibility to have access to data, data file will
be sent within 10 days.

Comments