

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Sep 2026

Effect patient and staff education programs to decrease falls and fall-related injuries in a general hospital: cluster randomized controlled trial

Protocol summary

Summary

This study is a cluster randomized controlled trial using stepped wedge method for examining effectiveness of multiple intervention strategy in reducing patients' fall and fall-related injuries for 38 weeks in a general hospital. The units (clusters) are determined by random allocation before the start of the trial for entrancing to the intervention phase at specific period of times (2 weeks). All clusters start the trial in a control phase with no intervention being delivered in any of them and then sequentially cross over from the control group to the intervention group, until all units are receiving the intervention. Inclusion criteria: All patients admitted to 18 units with a Morse risk score more than 45; patients with a history of fall and exclusion criteria: Patients with a Morse risk score less than 45. The primary and secondary outcome measures will be patient fall during hospitalization and fall-related injuries, their treatments respectively. The number of patient admissions to the unit and the number of patient bed days (LOS for each patient) will be collected routinely at each unit. The sample size used in this study is calculated based on Woertman's study formula. Our hypothesis is that the interventions will a reduction of 30 percent on the incidence in fall rate. The required sample size was calculated to be 2100, using an alpha of 0.05 and desired power level of 0.90. Interventions of the study are as follows: patient education, staff training, training patients for not leaving the bed and the bathroom without asking for help, placement of nursing-call bells, Provide adequate lighting, supervise high risk patients during transmission and handovers, allocate mobility devices, placement of call bell and safe guard in bathrooms, placement of a 'Fall alert' sign above the patient's bed, detection and treatment of postoperative complications such as Hypoxia, using yellow wristband, encourage appropriate use of eyeglasses, hearing aids and footwear, reassessment of patients after their fall, placing side rails on bed and encourage patients to

empty their bladder and bowel prior to bedtime.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015052022333N1**

Registration date: **2015-10-20, 1394/07/28**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-10-20, 1394/07/28

Registrant information

Name

zhila Najafpour

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8490 2117

Email address

zh-najafpour@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2015-11-11, 1394/08/20

Expected recruitment end date

2016-06-20, 1395/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect patient and staff education programs to decrease falls and fall-related injuries in a general hospital: cluster randomized controlled trial

Public title

prevention of patient fall

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: All patients admitted in 18 wards with a MORSE risk score more than 45; patients with a history of falls
Exclusion criteria: Patients with a MORSE risk score less than 45

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **2100**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Crossover

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee in Research affiliated of Tehran University of Medical Sciences

Street address

8th floor, center building of Tehran University of Medical Sciences, GHods street, Keshavarz boulevard, Tehran, Iran

City

Tehran

Postal code**Approval date**

2015-08-01, 1394/05/10

Ethics committee reference number

IR.TUMS.REC.1394.496

Health conditions studied**1****Description of health condition studied**

fall from bed, fall from wheelchair, fall from chair, fall from or off toilet

ICD-10 code

w05-w06-w0

ICD-10 code description

Fall involving bed, Fall involving wheelchair, Fall involving chair, other fall on same level

Primary outcomes**1****Description**

Patient fall during hospitalization

Timepoint

38 weeks

Method of measurement

patient interview, screening of medical record

Secondary outcomes**1****Description**

Fall-related injuries, their treatments and LOS (Length of stay)

Timepoint

38 weeks

Method of measurement

Observation, patient interview, physician assessment of patient's clinical condition and screening of medical record

Intervention groups**1****Description**

patient education, staff training, training patients for not leaving the bed and the bathroom without asking for help, placement of nursing-call bells, Provide adequate lighting, supervise high risk patients during transmission and handovers, allocate mobility devices, placement of call bell and safe guard in bathrooms, placement of a 'Fall alert' sign above the patient's bed, detection and treatment of postoperative complications such as Hypoxia, using yellow wristband, encourage appropriate use of eyeglasses, hearing aids and footwear, reassessment of patients after their fall, placing side rails on bed and encourage patients to empty their bladder and bowel prior to bedtime.

Category

Prevention

2

Description

Participants in the control phase receive usual care of hospital that consists of assessment of patients and having specific identification wristband.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Shariati hospital

Full name of responsible person

Dr. Ali Movafegh

Street address

Shariati hospital, at the begining of Jalale Al Ahmad avenue, Kargar's north street, Tehran, Iran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Mohamad Arab

Street address

Economic And Health Managment group, Public Health Faculty, Tehran university of medical sciences, Pour Sina street, 16 Azar street, Tehra, Iran

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

Tehran Univercity of Medical Sciences

Full name of responsible person

Dr.Mohammad Arab

Position

PHD health care managment

Other areas of specialty/work

Street address

Economic And Health Management group, Public Health Faculty, Tehran University of Medical Sciences, Pour Sina street, Keshavarz boulevard, Tehran, Iran

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Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Other areas of specialty/work

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Person responsible for updating data

Contact

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Full name of responsible person

Jila Najafpour

Position

PHD Health Care Managment

Other areas of specialty/work

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Web page address

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