

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Jun 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 trail

## 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 Committe in Resarech afiliated of Tehran Univercity of Medical Sciences

##### Street address

8th floor,center buliding of Tehran Univercity 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 management

**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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**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*