# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

09 Nov 2026

## The effect of clinical supervision model on the medication safety and knowledge of medication safety of nursing internship students of Isfahan University of Medical Sciences in 2021.

## Protocol summary

**Study aim**
Determining the effect of clinical supervision model on the medication safety and knowledge of medication safety of nursing internship students of Isfahan University of Medical Sciences in 2021.

**Design**
This study is a clinical trial with a control group, two-stage and before and after tests on 70 nursing internship students, one blind (statistical analyzer) and randomized by randomized block method.

**Settings and conduct**
The environment of this research is the hospitals affiliated to Isfahan University of Medical Sciences, where internship students are spending their shifts, and how to do the work is given in the intervention groups section.

**Participants/Inclusion and exclusion criteria**
Nursing internship students of the School of Nursing and Midwifery, Isfahan University of Medical Sciences / Admission requirements: 1. Students have entered the internship course,(nursing student in 7th semester) 2. Students have passed their pharmacology unit with a passing grade / Criteria for non-entry: Participation in classes medication safety, outside the university curriculum.

**Intervention groups**
the clinical supervision model is implemented in three stages for the intervention group. In the first stage, a session is held outside the student shift program, checklist items are explained to them and students' questions are answered. There is also a general agreement on what is to be done in Phase 2. In the second stage, the researcher comes to the hospitals and evaluates the students' performance according to the checklist, answers the students' questions and receives feedback from them. In the third stage, the students' opinions about the supervision model Clinically, its strengths and weaknesses are questioned. Normal and traditional monitoring is performed for the control group

**Main outcome variables**
medication safety of internship students؛ knowledge of medication safety of nursing students

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20170731035424N3**
Registration date: **2021-10-31, 1400/08/09**
Registration timing: **registered_while_recruiting**

Last update: **2021-10-31, 1400/08/09**
Update count: **0**

**Registration date**
2021-10-31, 1400/08/09

**Registrant information**

**Name**
Sedigheh Farzi

**Name of organization / entity**
Isfahan University of Medical Sciences

**Country**
Iran (Islamic Republic of)

**Phone**
+98 31 3792 7565

**Email address**
sedighehfarzi@nm.mui.ac.ir

**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2021-10-05, 1400/07/13

**Expected recruitment end date**
2021-11-21, 1400/08/30

**Actual recruitment start date**
empty
**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
The effect of clinical supervision model on the medication safety and knowledge of medication safety of nursing internship students of Isfahan University of Medical Sciences in 2021.

**Public title**
effect of an educational program on the medication safety and knowledge of medication safety
**Purpose**
Education/Guidance
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Students have entered the internship course Students have passed their pharmacology unit with a passing grade
**Exclusion criteria:**
Participate in medication safety classes outside the university curriculum
**Age**
No age limit
**Gender**
Both

**Phase**
N/A
**Groups that have been masked**

- Data analyser

**Sample size**
Target sample size: **70**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
In this study, we will use the block randomization method. Blocking is usually used to balance the number of samples assigned to each of the study groups. The size of all blocks is equal and we will have 4 groups of 4 blocks (including 2 participants in the intervention group and 2 participants in the control group) in this two-group experiment. In this way, we will have 18 blocks of 4 that will divide people into two groups of 36 people. Randomization tool also uses software random allocation software (Random allocation software) that these random sequence generation software in addition to simple randomization are able to generate random sequence by blocking method. Using opaque sealed envelopes, each of the random sequences created is recorded on a card, and the cards are placed inside the envelopes in order. In order to maintain a random sequence, the envelopes are numbered in the same way on the outer surface. Finally, the lids of the letter envelopes are glued and placed inside a box, respectively. At the beginning of the registration of participants, based on the order of entry of eligible participants into the study, one of the envelopes of the letter is opened in order and the assigned group of the participant is revealed.
**Blinding (investigator's opinion)**
Single blinded
**Blinding description**
The data analyzer will not know which of the two intervention and control groups the data being analyzed belongs to.
**Placebo**
Not used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Ethics Committee of Isfahan University of Medical Sciences
**Street address**
Hezar Jerib street
**City**
Isfahan
**Province**
Isfehan
**Postal code**
81746 73461
**Approval date**
2021-10-02, 1400/07/10
**Ethics committee reference number**
IR.MUI.NUREMA.REC.1400.124

## Health conditions studied

### 1

**Description of health condition studied**
In this study, no specific disease is examined
**ICD-10 code**
**ICD-10 code description**

## Primary outcomes

### 1

**Description**
Medication Safety Score by Medication Safety Critical Element Checklist
**Timepoint**
Before the intervention (in both intervention and control groups) and in each of the 5 sessions of the clinical supervision model in the intervention group (for the control group in 5 sessions with normal supervision)
**Method of measurement**
Medication Safety Critical Element Checklist

## Secondary outcomes

### 1

**Description**
Medication Safety Knowledge Assessment Score according to the Medication Safety Knowledge Assessment Questionnaire
**Timepoint**
Before and after the intervention (in both intervention and control groups)
**Method of measurement**
Medication Safety Knowledge Assessment Questionnaire

## Intervention groups

### 1

**Description**
"Intervention group:" The clinical supervision model for the intervention group is done in three stages: In the first stage, a session is held outside the student shift program, checklist items are explained to them and students' questions are answered. A general agreement is reached on what is to be done in step 2. In the second stage, the researcher comes to the hospitals and evaluates the students 'performance according to the checklist, answers the students' questions and receives feedback from them. This stage lasts for 5 weeks. And every week there is a monitoring of each student. In the third stage, students' opinions about the clinical supervision model, its strengths and weaknesses are asked.
**Category**
Other

### 2

**Description**
"Control group:" For the control group, 5 normal monitoring sessions are performed
**Category**
N/A

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
AL Zahra hospital
**Full name of responsible person**
Dr. Majid Rezvani
**Street address**
Isfahan - Sofa Boulevard
**City**
Esfahan
**Province**
Isfehan
**Postal code**
8174675731
**Phone**
+98 31 1668 5555
**Email**
alzahra@mui.ac.ir

### 2

**Recruitment center**
**Name of recruitment center**
Amin hospital
**Full name of responsible person**
Dr. Hamid Melali
**Street address**
Isfahan, Ibn Sina St., Sanbolistan Alley, Amin Hospital
**City**
Esfahan
**Province**
Isfehan
**Postal code**
۸۱۴۸۶۵۳۱۴۱
**Phone**
+98 31 1445 5051
**Email**
amin@mui.ac.ir

### 3

**Recruitment center**
**Name of recruitment center**
Kashani Hospital
**Full name of responsible person**
Dr. Seyed Taghi Hashemi
**Street address**
Isfahan, Ayatollah Kashani Main Street, Ayatollah Kashani Hospital
**City**
Esfahan
**Province**
Isfehan
**Postal code**
۸۳۴۳۴-۸۱۸۳۹
**Phone**
+98 31 1233 0091
**Email**
kashani@mui.ac.ir

### 4

**Recruitment center**
**Name of recruitment center**
Khurshid Hospital
**Full name of responsible person**
Dr. Ramin Sami
**Street address**
Esfahan - Hasht Behesht, Ostandari Street
**City**
Esfahan
**Province**
Isfehan
**Postal code**
۸۱۴۵۸۳۱۴۵۱
**Phone**
+98 31 1222 2127
**Email**

nour@mui.ac.ir

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Esfahan University of Medical Sciences
**Full name of responsible person**
Shaghayegh Hagh Jooi Javanmard
**Street address**
Hezar jerib Street
**City**
Isfahan
**Province**
Isfehan
**Postal code**
8174- 73461
**Phone**
+98 31 3792 2414
**Email**
sh_haghjoo@med.mui.ac.ir
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Esfahan University of Medical Sciences
**Proportion provided by this source**
100
**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**
Esfahan University of Medical Sciences
**Full name of responsible person**
Dr. Sedigheh Farzi
**Position**
Faculty of Isfahan University of Medical Sciences
**Latest degree**
Ph.D.
**Other areas of specialty/work**
Nursery
**Street address**
School of Nursing and Midwifery, Department of Adult Health Nursing
**City**
Isfahan
**Province**
Isfehan
**Postal code**
81746-73461
**Phone**
+98 31 3792 7589
**Email**
Sedighehfarzi@nm.mui.ac.ir

## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Esfahan University of Medical Sciences
**Full name of responsible person**
Dr. Sedigheh Farzi
**Position**
Faculty of Isfahan University of Medical Sciences
**Latest degree**
Ph.D.
**Other areas of specialty/work**
Nursery
**Street address**
Isfahan School of Nursing and Midwifery, Department of Adult Health Nursing
**City**
Isfahan
**Province**
Isfehan
**Postal code**
81746-73461
**Phone**
+98 31 3792 7589
**Email**
Sedighehfarzi@nm.mui.ac.ir

## Person responsible for updating data

**Contact**
**Name of organization / entity**
Esfahan University of Medical Sciences
**Full name of responsible person**
Dr. Sedigheh Farzi
**Position**
Faculty of Isfahan University of Medical Sciences
**Latest degree**
Ph.D.
**Other areas of specialty/work**
Nursery
**Street address**
Isfahan School of Nursing and Midwifery, Department of Adult Health Nursing
**City**
Isfahan
**Province**
Isfehan
**Postal code**
81746-73461
**Phone**
+98 31 3792 7589
**Email**
Sedighehfarzi@nm.mui.ac.ir

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Yes - There is a plan to make this available
**Study Protocol**
Yes - There is a plan to make this available
**Statistical Analysis Plan**
Yes - There is a plan to make this available
**Informed Consent Form**
Yes - There is a plan to make this available
**Clinical Study Report**
Yes - There is a plan to make this available
**Analytic Code**
Yes - There is a plan to make this available
**Data Dictionary**
Yes - There is a plan to make this available
**Title and more details about the data/document**
By maintaining the confidentiality of participants' personal characteristics, the results of the study are shared based on the objectives of the study.
**When the data will become available and for how long**
Start the access period immediately after the results are published in reputable journals
**To whom data/document is available**
If a request is sent to the author in charge of the article, in order to prevent breach of confidentiality of the information of the participants in the study, the study will be done and a decision will be made about access to the results.
**Under which criteria data/document could be used**
If a request is sent to the author in charge of the article, in order to prevent breach of confidentiality of the information of the participants in the study, the study will be done and a decision will be made about access to the results.
**From where data/document is obtainable**
You can correspond with the responsible author via the email contained in the article to receive data.
**What processes are involved for a request to access data/document**
A request can be made by correspondence with the author of the article via email.
**Comments**