

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 2026

### Investigating the impact of applying the comprehensive patient assessment tool on the clinical decision making of nurses in Intensive Care Units of selected hospitals of Isfahan University of Medical Sciences in 2023

#### Protocol summary

##### Study aim

Investigating the impact of applying the comprehensive patient assessment tool on the clinical decision making of nurses in Intensive Care Units of selected hospitals of Isfahan University of Medical Sciences in 2023

##### Design

A clinical trial with a control group, a blind strain, an easy sampling method, random based on a table of random numbers, the sample number is 78 nurses.

##### Settings and conduct

Location: special care department of Al-Zahra Hospital, Isfahan. Examination of clinical decision-making in two groups before the intervention and then one month later is done using the standard questionnaire of Laurie's clinical decision-making. The test group will also complete the comprehensive patient health assessment tool in addition to the common method used in the intensive care unit, and the control group will only complete the patient care sheet. After the 1-month period, the clinical decision-making questionnaire will be completed again by the nurses in the control and test groups. It is a blind strain of nurses.

##### Participants/Inclusion and exclusion criteria

Entry: Nurses with a bachelor's degree or higher and with at least 6 months of work experience in the intensive care unit. Non-entry: Nurses with less than six months of work experience in the intensive care unit

##### Intervention groups

The aim of the study is to use a comprehensive patient health assessment tool and its impact on the clinical decision-making of special care nurses. In addition to the common method used in the intensive care unit, the test group will also complete the comprehensive patient health assessment tool, and the control group will only complete the patient care sheet in the intensive care unit.

#### Main outcome variables

Clinical decision making

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230730058967N1**

Registration date: **2023-08-16, 1402/05/25**

Registration timing: **prospective**

Last update: **2023-08-16, 1402/05/25**

Update count: **0**

##### Registration date

2023-08-16, 1402/05/25

##### Registrant information

##### Name

Maryam Hasandae Talkhonchek

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3680 1880

##### Email address

maryamhasandae@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-09-23, 1402/07/01

##### Expected recruitment end date

2023-12-22, 1402/10/01

##### Actual recruitment start date

empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
Investigating the impact of applying the comprehensive patient assessment tool on the clinical decision making of nurses in Intensive Care Units of selected hospitals of Isfahan University of Medical Sciences in 2023

**Public title**  
The effect of using a comprehensive patient health assessment tool for clinical decision-making by nurses in special care units

**Purpose**  
Other

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
1. Nurses working in the special care department who wish to continue participating in the study.2. Nurses working in the special care department who have a bachelor's degree or higher.3. Nurses working in intensive care units who have at least 6 months of experience in intensive care units.4. The employment status of nurses is permanent or contractual.  
**Exclusion criteria:**  
The employment status of nurses should be corporate. Work experience of less than six months in intensive care units

**Age**  
No age limit

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**  

- Participant

**Sample size**  
Target sample size: 78

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Randomization method: simple randomization, randomization unit: individual, randomization tool: like the table of random numbers and according to the rules of the table of random numbers The sampling method will be easy. These meanings are sampled from nurses working in special departments who are included in the study after completing the consent form. The samples are randomly placed in 2 control and test groups based on the random number table and according to the rules of the random number table. However, in order to avoid the influence of the control group on the test group, first the control group will enter the study and complete the clinical decision making questionnaire, and after a month has passed and the nurses of the control group have completed the questionnaire, the intervention will be done for the test group and the qualification questionnaire will be done. Clinical before and after one

month will be completed by nurses in the test group.

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
Nurses participating in this study are kept blind.

**Placebo**  
Not used

**Assignment**  
Other

**Other design features**  
This study is a two-group clinical trial study, the samples of which will be nurses working in the special care department. In addition to the common method used in the intensive care unit, i.e. completing the patient care sheet, the test group will also complete the comprehensive patient health assessment tool, and the control group will only complete the patient care sheet in the intensive care unit. But in order to prevent the influence of the control group from the test group, the control group will be included in the study first.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Esfahan University of Medical Sciences

##### Street address

Nursing and Midwifery College., Isfahan University of Medical Sciences and Health Services, Hazar Jarib St

##### City

Esfahan

##### Province

Isfahan

##### Postal code

8174673461

#### Approval date

2023-07-29, 1402/05/07

#### Ethics committee reference number

IR.MUI.NUREMA.REC.1402.062

## Health conditions studied

### 1

#### Description of health condition studied

Clinical decision making , comprehensive patient assessment

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Clinical decision making

#### Timepoint

Examination of clinical decision-making in two control and test groups before the intervention and after one month is carried out by using Laurie's standard clinical decision-making questionnaire.

#### Method of measurement

Laurie standard clinical decision making questionnaire

### Secondary outcomes

empty

### Intervention groups

#### 1

##### Description

Intervention group: In this study, in order to perform a comprehensive patient health assessment using the m.score comprehensive patient health assessment tool) by the nurses of the special care department in the test group to examine the patients hospitalized in the department in all three shifts, when the patient is handed over to the next shift manager at the end of the shift. and also providing reports to specialist doctors at the time of the patient's visit based on the relevant tools used.

##### Category

Other

#### 2

##### Description

Control group: Intensive care nurses do not receive any intervention.

##### Category

Other

### Recruitment centers

#### 1

##### Recruitment center

###### Name of recruitment center

Al-Zahra Hospital

###### Full name of responsible person

Somayeh Ghaffari

###### Street address

No 761, Milad noor4the alley, Milad noor Ave, Eastern olfat Ave, Baharestan

###### City

Esfahan

###### Province

Isfahan

###### Postal code

8145116531

###### Phone

+98 913 688 6308

###### Email

maryamhasandae@yadoo.com

### Sponsors / Funding sources

#### 1

##### Sponsor

###### Name of organization / entity

Esfahan University of Medical Sciences

###### Full name of responsible person

Somayeh Ghaffari

###### Street address

Nursing and Midwifery College, Isfahan University of Medical Sciences and Health Services, Hazar Jarib St

###### City

Esfahan

###### Province

Isfahan

###### Postal code

8174673461

###### Phone

+98 31 3668 0048

###### Email

somayehghafari@nm.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

Somayeh Ghaffari

###### Position

Assistant Professor

###### Latest degree

Ph.D.

###### Other areas of specialty/work

Nursery

###### Street address

Nursing and Midwifery College, Isfahan University of Medical Sciences and Health Services, Hazar Jarib St

###### City

Esfahan

###### Province

Isfahan

###### Postal code

8174673461

**Phone**

+98 31 3668 0048

**Email**

somayehghafari@nm.mui.ac.ir

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Somayeh Ghaffari

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**

Nursing and Midwifery College, Isfahan University of Medical Sciences and Health Services, Hazar Jarib St

**City**

Esfahan

**Province**

Isfahan

**Postal code**

8174673461

**Phone**

+98 31 3668 0048

**Email**

somayehghafari@nm.mui.ac.ir

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Somayeh Ghaffari

**Position**

Associate professor

**Latest degree**

Ph.D.

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## 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**

All data is potentially shareable after de-identifying individuals

**When the data will become available and for how long**

The access period starts 6 months after the results are published

**To whom data/document is available**

students of University Isfahan Medical Sciences and nurses working in Isfahan Medical Sciences Hospitals

**Under which criteria data/document could be used**

Use of documentation at the patient's bedside

**From where data/document is obtainable**

Isfahan University of Medical Sciences Postal code: 8174673461 or university digital library

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

Data can be obtained through the library

**Comments**