Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 Oct 2026

Comparing The Effectiveness of Using Evidence-Based Care Packages By Emergency Nurses On on The Hemodynamic Status of Brain Trauma Patients

Protocol summary

Study aim

Comparison of the effect of emergency nurses' performance on the hemodynamic status of brain trauma patients before and after using the evidence-based care package in two control and intervention groups.

Design

A semi-experimental clinical trial of control and intervention type, with parallel, randomized groups, is conducted on 60 nurses working in the emergency department of the main trauma centers in Tehran.

Settings and conduct

The research environment is the main trauma centers of Tehran. The selection of 60 nurses from the studied hospitals and their allocation to two control and intervention groups are done randomly. Then, the average effect of applying the evidence-based care package by emergency nurses on the hemodynamic status of brain trauma patients in two groups before and after the intervention will be investigated and compared by the care management checklist of brain trauma patients.

Participants/Inclusion and exclusion criteria

Entry Criteria Having at least 6 months of continuous clinical work experience in the emergency department of a hospital Having at least a bachelor's degree in nursing. Exit criteria: Participation in research or similar training courses, simultaneously with the present study Transfer to other centers, transfer to other departments, sick leave or immigration.

Intervention groups

30 nurses receive the evidence-based training package on the care of brain trauma patients and 30 others are placed in the control group. Using a checklist, the results before and after the intervention are checked and compared.

Main outcome variables

Hemodynamic Status of Brain Trauma Patients

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230126057239N1**
Registration date: **2023-03-11, 1401/12/20**
Registration timing: **registered_while_recruiting**

Last update: **2023-03-11, 1401/12/20**
Update count: **0**

Registration date

2023-03-11, 1401/12/20

Registrant information

Name

Shiva Yousefi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4454 7203

Email address

shivayousefi@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-03-06, 1401/12/15

Expected recruitment end date

2023-06-05, 1402/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparing The Effectiveness of Using Evidence-Based Care Packages By Emergency Nurses On on The Hemodynamic Status of Brain Trauma Patients

Public title
The Effect Of Using Evidence-Based Care Package in brain trauma

Purpose
Other

Inclusion/Exclusion criteria

Inclusion criteria:
For nurses, having at least a bachelor's degree and at least 6 months of continuous clinical work experience in the emergency department of the hospital For patients, the presence of moderate to severe head trauma based on the GCS criterion and the diagnosis of the attending physician

Exclusion criteria:
for nurses, participating in research or similar training courses, simultaneously with the present study; transfer to another department, transfer to other medical centers, sick leave, immigration; Absence in more than 2 training sessions and not being able to make up for the sessions For patients, death or transfer to departments other than trauma emergency before completion of checklists

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
In order to carry out this research, multi-stage sampling will be done. First, the selection of trauma centers is done by random cluster method, in this way, Tehran is divided into four parts (clusters) North, South, East and West, and one hospital with a trauma center is selected from each region. And then in these centers, 60 nurses will be selected by quota sampling method, in such a way that the selection is improbable and among the people in the available units, but it will be proportional to the number of nurses working in the selected hospitals. Then the allocation of nurse samples to groups will be done randomly and based on lottery. To select patients with moderate to severe trauma, through available sampling during 8 weeks during the work shifts of these nurses, 3 patients who meet the criteria for entering the research are selected and included in the study. To prevent leakage of information between the two groups, first the control group and then the intervention group are examined.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
First, the demographic information questionnaire is completed by the nurses of both groups in the first meeting, and then the quality of the emergency nurse's usual care of patients with moderate to severe brain trauma and the hemodynamic status of these patients, through the management checklist of patients with moderate to severe head trauma. It is completed by the researcher and the researcher's colleague through monitoring the hemodynamic status of the patients and also reviewing the documentation of their files, during the work shifts of these nurses for 3 patients with moderate to severe head trauma.After completing the checklist in the first stage, these nurses will be trained in the management of moderate to severe brain trauma patients based on the evidence-based care package, through 4 2-hour training workshops (during 2 weeks); After the end of the intervention, for each nurse to implement the instructions on 3 patients by monitoring the patient's hemodynamic status for a period of eight weeks, it is again evaluated by the same initial checklist and the average of the patient's hemodynamic status is determined. Finally, the hemodynamic status of the patients before and after the intervention will be compared and analyzed.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shahid Beheshti School of Midwifery Nursing

Street address
No. 33, Panzdeh East Alley, Shahid Sadoqi Street, Yas Blvd., Tehran, Sar

City
Tehran

Province
Tehran

Postal code
1388973586

Approval date
2022-08-15, 1401/05/24

Ethics committee reference number
IR.SBMU.PHARMACY.REC.1401.104

Health conditions studied

1

Description of health condition studied
Brain Trauma

ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Hemodynamic Status of Brain Trauma Patients
Timepoint
8 weeks
Method of measurement
Care management checklist for brain trauma patients

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:60 nurses are randomly selected and placed in two control and intervention groups. In the intervention group, firstly, the effect of the performance of 30 nurses on the hemodynamic status of brain trauma patients is investigated using the brain trauma patients management checklist for a period of 8 weeks. 3 patients are evaluated for each nurse; Then they are trained in the management of brain trauma patients based on the evidence-based care package, through 4 two-hour training workshops; And within eight weeks after the end of the sessions, their performance in the field of caring for these patients will be evaluated again by the same checklist. The results of two tests of the control group and the results of two tests of the intervention group are also compared. Also, the results of the control and intervention groups will be compared.
Category
N/A

2

Description
Control group: There was no intervention in the control group, and the effect of the performance of 30 nurses in the control group on the hemodynamic status of brain trauma patients was investigated using the brain trauma patients management checklist. 3 patients are evaluated for each nurse. Again, 8 weeks later, the effect of the performance of 30 nurses in the control group on the hemodynamic status of brain trauma patients will be evaluated by the same checklist.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Taleghani Hospital, Imam Hossein, Luqman and Shohada Haftom Tir Hospital
Full name of responsible person
Shiva Yousefi
Street address
No. 33, Panzdeh East Alley, Shahid Sadoqi Street, Yas Blvd., Tehran, Sar
City
Tehran
Province
Tehran
Postal code
1388973586
Phone
+98 21 4454 7203
Email
shivayousefi@sbmu.ac.ir
Web page address
https://hospht.iums.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr. Afshin Zarghi
Street address
No. 33, Panzdeh East Alley, Shahid Sadoqi Street, Yas Blvd., Tehran, Sar
City
Tehran
Province
Tehran
Postal code
1388973586
Phone
+98 21 4454 7203
Email
shivayousefi@sbmu.ac.ir
Web page address
https://research.sbmu.ac.ir/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
shiva yousefi

Position
Nursing master's student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

Street address
No. 33, Panzdeh East Alley, Shahid Sadoqi Street, Yas Blvd., Tehran, Sar

City
Tehran

Province
Tehran

Postal code
1388973586

Phone
+98 21 4454 7203

Email
shivayousefi@sbmu.ac.ir

Web page address
https://www.sbmu.ac.ir/

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Dr. Seyedeh Narjes Mousavizadeh

Position
Assisstant professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

Street address
No. 33, Panzdeh East Alley, Shahid Sadoqi Street, Yas Blvd., Tehran, Sar

City
Tehran

Province
Tehran

Postal code
1388973586

Phone
+98 21 4454 7203

Email
n.mousavi@sbmu.ac.ir

Web page address
https://www.sbmu.ac.ir/

Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
shiva yousefi

Position
Nursing master's student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

Street address
No. 33, Panzdeh East Alley, Shahid Sadoqi Street, Yas Blvd., Tehran, Sar

City
Tehran

Province
Tehran

Postal code
1388973586

Phone
00989 021 44547203

Email
shivayousefi@sbmu.ac.ir

Web page address
https://www.sbmu.ac.ir/

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available