Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

A comparative study on the effect of using the modified World Health Organization trauma cares checklist and standard World Health Organization trauma cares checklist on morbidity and mortality among traumatic patients

Protocol summary

Study aim
The effectiveness of modified World Health Organization's checklist on mortality/ Morbidity of Traumatic patients

Design
First, the patients will be evaluated according to the demographic and numerical scale of the pain and the severity of the trauma. The patients were then randomly assigned into three groups: (1) routine without using the checklist (control group), (2). In accordance with the WHO checklist (intervention group A) and (3). The modified checklist (the second intervention group). Patients are assessed for pain intensity, severity of injury, mortality/ morbidity and complications for one month after entering the study. The results will compare at the end.

Settings and conduct
This study is done in patients referring to the trauma center of Taleghani Hospital of Kermanshah University of Medical Sciences. Double blind is done for all patients and who analyzes the data.

Participants/Inclusion and exclusion criteria
Criteria for entering the study: 1) Traumatic patients aged 18 to 60 years and GCS greater than or equal to 10 2) The existence of a specific field of life threatening organs based on the judgment of the therapist 3) Patients who need trauma team services Exit criteria: 1- Pregnancy 2. Unwillingness to participate in the study 3. Patients with a history of chronic psychiatric, pulmonary, renal disease or chemotherapy patients. 4. Drug addiction

Intervention groups
Control group: Patients treated routinely without using the checklist. First intervention group: They are treated with the WHO checklist. Second intervention group: Treated by the modified WHO checklist

Main outcome variables
Mortality rate; Type and number of complications following trauma; Duration of hospitalization

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20081007001310N12**
Registration date: **2018-09-15, 1397/06/24**
Registration timing: **retrospective**

Last update: **2018-09-15, 1397/06/24**
Update count: **0**

Registration date
2018-09-15, 1397/06/24

Registrant information

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Alireza Ahmadi
Name of organization / entity
Kermanshah University of Medical Sciences
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-03-06, 1396/12/15

Expected recruitment end date

2018-09-06, 1397/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study on the effect of using the modified World Health Organization trauma cares checklist and standard World Health Organization trauma cares checklist on morbidity and mortality among traumatic patients

Public title

The effect of World Health Organization modified checklist on the complications and mortality rate of trauma patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

GCS equal to or greater than 10 The existence of a specific life threatening event for organs, based on the judgment of the therapist Patients need trauma team services

Exclusion criteria:

Pregnancy Unwillingness to participate in the study Patients with a history of chronic psychiatric, pulmonary, renal disease or chemotherapy drug addiction

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **180**

Randomization (investigator's opinion)

Randomized

Randomization description

Method of randomization: simple randomization; Unit of randomization: patients; Tools used for randomization: random allocation software

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, all participants, the main researcher, data collection and outcome assessors, the Data Safety and Monitoring Board's safety and data monitoring committee, and those who prepare the draft of article are blind. However, health personnel and doctors who are responsible for providing services to patients in the Emergency Department are not blind. But doctors and nurses in after emergency wards are blind in the hospital.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Kermanshah University of Medical Sciences

Street address

Imam Reza Hospital, Zakariya Razi Blvd, Kermanshah, Iran

City

Kermanshah

Province

Kermanshah

Postal code

6718818838

Approval date

2017-11-30, 1396/09/09

Ethics committee reference number

IR.KUMS.REC.1396.535

Health conditions studied

1

Description of health condition studied

trauma

ICD-10 code

G89.11

ICD-10 code description

Acute pain due to trauma

Primary outcomes

1

Description

Mortality rate

Timepoint

Three months after entering the study

Method of measurement

By referring to patients' documents files in hospital and telephone contacts with patients or visiting patients place of residence.

2

Description

severity of complications of patients

Timepoint
Three months after entering the study
Method of measurement
The Injury Severity Score (ISS)

3

Description
duration of hospitalization
Timepoint
Three months after entering the study
Method of measurement
World Health Organization Trauma Care Checklist

Secondary outcomes

1

Description
Patient Satisfaction
Timepoint
Three days after hospitalization
Method of measurement
Visual Analogue Scale

Intervention groups

1

Description
Intervention group 1 (standard). care services are based on the standard WHO Trauma Care Checklist. This checklist contains several intervention items such as airway control, blood coagulation control, hemothorax, examination, and so on. In this traumatic patients group, the services in the emergency department are provided according to this checklist.
Category
Treatment - Other

2

Description
Intervention Group (2): receives medical treatment based on WHO modified checklist with focusing on pain management (intervention items are as follows: airway intervention control, internal hemorrhage control and hemothorax diagnosis, etc)
Category
Treatment - Other

3

Description
Control Group: receives routine medical treatment without using checklist
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Ayatollah Taleghani Hospital, Beheshti Boulevard, Kermanshah, Iran
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kermanshah 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
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Full name of responsible person
Alireza Ahmadi
Position
Assistant profossor
Latest degree
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Other areas of specialty/work
Anesthesiology
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Person responsible for updating data

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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
data set will be shared after the anonymity of patients.
When the data will become available and for how long
The open access period is 6 months after publication of the results.
To whom data/document is available
All people
Under which criteria data/document could be used
All analyzes and all data
From where data/document is obtainable
By email or by phone: 00989188581019
ahmadiar1012@yahoo.com
What processes are involved for a request to access data/document
As soon as the request is received, we will send the requested items .
Comments