

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 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

Name

Alireza Ahmadi

Name of organization / entity

Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 3428 2670

Email address

info-jivr@kums.ac.ir

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

Alireza Ahmadi

Street address

Ayatollah Taleghani Hospital, Beheshti Boulevard, Kermanshah, Iran

City

Kermanshah

Province

Kermanshah

Postal code

6718818838

Phone

+98 83 3428 2670

Fax

+98 83 3428 2670

Email

ahmadiar1012@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Farid Najafi

Street address

Zakariya Razi Blvd, Kermanshah, Iran.

City

Kermanshah

Province

Kermanshah

Postal code

6718818838

Phone

+98 83 3428 2670

Email

fnajafi@yahoo.com

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

Kermanshah University of Medical Sciences

Full name of responsible person

Alireza Ahmadi

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

Imam Reza Hospital, Zakariya Razi Blvd, Kermanshah, Iran.

City

Kermanshah

Province

Kermanshah

Postal code

6718818838

Phone

+98 988334282670

Email

ahmadiar1012@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Alireza Ahmadi

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

Imam Reza Hospital, Zakariya Razi Blvd, Kermanshah, Iran.

City

Kermanshah

Province

Kermanshah

Postal code

6718818838

Phone

+98 83 3428 2670

Email

ahmadiar1012@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Alireza Ahmadi

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

Imam Reza Hospital, Zakariya Razi Blvd, Kermanshah, Iran.

City

Kermanshah

Province

Kermanshah

Postal code

6718818838

Phone

+98 83 3428 2670

Email

ahmadiar1012@yahoo.com

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