

# 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

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#### **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.

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#### **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.

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

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**Full name of responsible person**

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**Position**

Assistant professor

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Alireza Ahmadi

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Assistant Professor

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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**