

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jun 2026

### The effect of using critical care service team in comparison to routine care on mortality of acutely ill patients in general wards

#### Protocol summary

##### Summary

Delivering timely, safe, and optimal care to patients is an unalienable obligation of a health system and its workers; sub-optimal care, as a rule, ends up with deteriorating conditions for patients. This is certainly the case in general hospital wards, where an increasing number of acutely ill patients (AIP) are admitted. Failing to identify and manage AIPs may lead to catastrophic outcomes. Implementing a Critical Care Service (CCS), aimed at timely identification and management of AIPs, was an approach to overcoming these shortcomings. An evaluation study is designed to explore the potential impact of CCS in 13 medical-surgical wards in an Iranian University Hospital during the 72-week period. The study design is a Stepped-Wedge Cluster Randomized Controlled Trial. The study include, for each ward, an unexposed to the intervention phase, a training phase, and an exposed to the intervention phase during which the ward go through a transition phase of adopting the intervention (CCS). All patients care for during the unexposed; training and exposed to the intervention phases are included as unexposed, training, and exposed respectively. Burn, cardiac surgery, pediatric and neonatal will exclude from the study. The CCS team is nurse-led, and the CCS team members have responsibility for training and assisting the ward staff in caring for the AIPs. The primary outcomes are CPRs and mortality, and the secondary outcomes are length of stay and admission to intensive care unit. The outcomes in two phases will be compared, when the ward patients receive routine care and later on when the CCS will be implemented in the wards.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201107187053N1**

Registration date: **2015-07-07, 1394/04/16**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2015-07-07, 1394/04/16

##### Registrant information

###### Name

Alireza Jeddian

###### Name of organization / entity

Tehran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 8490 2101

###### Email address

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##### Recruitment status

**Recruitment complete**

##### Funding source

Vice Chancellor for research, Tehran University of Medical Sciences

##### Expected recruitment start date

2010-07-17, 1389/04/26

##### Expected recruitment end date

2012-01-17, 1390/10/27

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of using critical care service team in comparison to routine care on mortality of acutely ill patients in general wards

## Public title

The effect of using critical care service team on mortality of acutely ill patients

## Purpose

Health service research

## Inclusion/Exclusion criteria

Inclusion criteria: The role of CCS is to deliver care in the non-critical care units of general hospital wards and all patients who will admit to these wards were included in the trial. Exclusion criteria are burn;cardiac surgery; pediatric and neonatal patients .

## Age

From **18 years** old to **120 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size:

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Other

## Other design features

Assigning the participating wards to the intervention was at random

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Tehran university of medical sciences

##### Street address

Ghods St., Keshavarz Blvd, Tehran

##### City

Tehran

##### Postal code

1417653761

#### Approval date

2010-08-20, 1389/05/29

#### Ethics committee reference number

89-01-37-10612

## Health conditions studied

### 1

#### Description of health condition studied

Acutely Ill Patients

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Number of deaths

#### Timepoint

during three phases of receiving routine care, while on training and while receiving intervention

#### Method of measurement

Physician's certification of death

### 2

#### Description

Number of Cardio-pulmonary resuscitations

#### Timepoint

during three phases of receiving routine care, while on training and while receiving intervention

#### Method of measurement

A CPR call that was made for the patient (was called code 145 in study setting) and completed CPR forms in the medical records of the patient

## Secondary outcomes

### 1

#### Description

Length of stay

#### Timepoint

during three phases of receiving routine care, while on training and while receiving intervention

#### Method of measurement

Total days of patients hospitalization according to the hospital information system

### 2

#### Description

Admission to ICU

#### Timepoint

during three phases of receiving routine care, while on training and while receiving intervention

#### Method of measurement

Number of patient who will admit to the ICU from general wards (medical and surgical)

## Intervention groups

### 1

#### Description

The intervention group: In this study the intervention group will receive the critical care service (CCS). The

steps of intervention will be training of ward nurses, admitting acutely ill patients (AIPs) under the care of CCS and management and follow up of CCS patients. These steps explain in detail as below: 1- Training of ward nurses : Because ward nurses are the first step in the CCS process, an additional 8-week period of training is provided for them before starting the intervention on each ward. During this stage identifying the acutely ill patients , the process of CCS and patients care will explained to ward staff. 2- Admitting AIPs under the care of CCS: Patients can come under the care of the CCS in one of three ways: a) patients who met the criteria (for example: high blood pressure ( are referred by the ward staff to the CCS team; b) patients will discharge from ICU; and c) the CCS team can actively identify patients in the wards. Ward nurses will identify patients requiring intervention by the CCS based on the standard criteria. The ward nursing staff will report any changes in systolic blood pressure, respiratory rate, heart rate, urinary output, body temperature, level of consciousness and any other general concerns about the patient's condition to the shift's head nurse. They will continue to observe the patients for 30 minutes, and if there is no improvement; they will inform the CCS team. Then the CCS team will attend the patient's bedside. The patient's care is taken over by the CCS team if the patient has a acute condition. If the patient is assess and find not to need CCS (those with no acute condition), they are given the same treatments as other patients in wards. Also, list of patients, who are transfer from ICUs to general wards, is taken from supervisors in each shift and pass to the CCS team. Following these patients are visit by CCS team members and place in CCS team service. 3- Management and follow up of CCS patients: After admitting patients to CCS, immediate evaluations are carried out and decisions are made for their management. Methods for patients' management are applied to CCS patients, as will describe below: a) Active intervention: In these situations, team members are responsible for patients' critical care, such as airway suction, changes in patients' position, oxygen therapy, and consultation with physicians about patient care. b) Training of ward staff: Medical staffs, particularly wards nurses, are trained in patient care. This include appropriate airway management, suction, oxygen therapy, changing the patient's position, endotracheal tube care, working with a ventilator and regulating its settings based on the patient's needs. The team members give practical tutoring to the staff on the correct performance of these procedures. c) Training and active intervention: This method is a combination of previous methods. After intervention, haemodynamically stable patients are observed for 72hours and then discharge from CCS if they recover. If not, another intervention is decided upon. Patients who remain ill and unstable, or whose conditions cause concern, are transferred to ICU if there are any empty beds available. If not, the intervention is continued on general wards.

**Category**

Treatment - Other

**2**

**Description**

Control group: This group will receive routine ward care and usual practices vis-a-vis urgent patient situations

**Category**

Other

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Shariati Hospital

**Full name of responsible person**

Alireza Jeddian

**Street address**

Shariati Hospital, Jalal alahmad, North Kargar, Tehran

**City**

Tehran

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Vice chancellor for research, Tehran University of Medical Sciences

**Full name of responsible person**

Dr Akbar Fotouhi

**Street address**

Ghods St, Keshavarz Boulevard

**City**

Tehran

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice chancellor for research, Tehran University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

empty

**Domestic or foreign origin**

empty

**Category of foreign source of funding**

empty

**Country of origin**

**Type of organization providing the funding**

empty

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

Tehran University of Medical sciences

**Full name of responsible person**

Alireza Jeddian

**Position**

MD

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**Email**

**Web page address**

**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*