

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)

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+98 21 8490 2101

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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

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Alireza Jeddian

Position

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Other areas of specialty/work

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Full name of responsible person

Alireza Jeddian

Position

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Other areas of specialty/work

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City

Tehran

Postal code

Phone

Fax

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