

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Comparison of rescue blankets with conventional blankets to prevent hypothermia in patients transmitted by emergency medical service

Protocol summary

Study aim

- Determining the effectiveness of rescue blankets on patients' cold discomfort scale - Determining the effectiveness of conventional blankets on patients' cold discomfort scale - Determining the effectiveness of rescue blankets on patients' vital signs - Determining the effectiveness of conventional blankets on patients' vital signs

Design

Two arm parallel group randomised trial with non-blinded outcome assessment

Settings and conduct

All patients who are transferred from the scene to the emergency department of Hospital, meet the inclusion and exclusion criteria, will be entered in the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: - Age over 18-year-old - Cold discomfort scale over 2 Exclusion criteria: - Glasgow coma scale less than 15 - Transfer time from scene to hospital less than 10 minutes - Transfer with helicopter

Intervention groups

In one group, patients are covered by a rescue blanket from the scene to the hospital during transferring by emergency medical service, and in the other group, conventional blankets are used for patients.

Main outcome variables

Cold discomfort scale Vital signs including tympanic temperature, blood pressure, pulse rate, respiratory rate and O₂-saturation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190416043288N1**

Registration date: **2019-04-24, 1398/02/04**

Registration timing: **retrospective**

Last update: **2019-04-24, 1398/02/04**

Update count: **0**

Registration date

2019-04-24, 1398/02/04

Registrant information

Name

Alireza Baratloo

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-20, 1397/12/01

Expected recruitment end date

2019-03-19, 1397/12/28

Actual recruitment start date

2019-02-20, 1397/12/01

Actual recruitment end date

2019-03-20, 1397/12/29

Trial completion date

2019-04-20, 1398/01/31

Scientific title

Comparison of rescue blankets with conventional blankets to prevent hypothermia in patients transmitted by emergency medical service

Public title

Efficiency of Rescue Blankets vs. Conventional Blankets in Pre-Hospital Phase

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Age over 18-year-old Cold Discomfort Scale over 2

Exclusion criteria:

Glasgow coma scale less than 15 Transfer time from the scene to the hospital less than 10 minutes Transmission with helicopter

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **200**

Actual sample size reached: **200**

Randomization (investigator's opinion)

Randomized

Randomization description

Two regional ambulance stations were selected to participate in this study, which transmits patients to a single hospital. One uses rescue blanket during transferring all patients. Another one use conventional blanket for transferring all patients.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Vice Chancellor in Research Affairs - Tehran
University of Medical Sciences

Street address

Central building of Tehran University of Medical
Sciences, Ghods Sreet, Keshavarz Boulevard

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2019-03-08, 1397/12/17

Ethics committee reference number

IR.TUMS.VCR.REC.1397.1092

Health conditions studied**1****Description of health condition studied**

Traumatic and non-traumatic patients transferred to the hospital by emergency medical service

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

The severity of the patient discomfort from the cold

Timepoint

Before moving the ambulance from the scene and at the time of the patient's delivery to the emergency department of the destination hospital

Method of measurement

Cold Discomfort Scale

2**Description**

Patient's body temperature

Timepoint

Before moving the ambulance from the scene and at the time of the patient's delivery to the emergency department of the destination hospital

Method of measurement

Tympanic temperature

Secondary outcomes**1****Description**

Blood pressure

Timepoint

Before moving the ambulance from the scene and at the time of the patient's delivery to the emergency department of the destination hospital

Method of measurement

Millimeter mercury

2**Description**

Pulse rate

Timepoint

Before moving the ambulance from the scene and at the time of the patient's delivery to the emergency department of the destination hospital

Method of measurement

Beat per minute

3**Description**

Respiratory rate

Timepoint

Before moving the ambulance from the scene and at the time of the patient's delivery to the emergency department of the destination hospital

Method of measurement

number per minute

4**Description**

O2 saturation

Timepoint

Before moving the ambulance from the scene and at the time of the patient's delivery to the emergency department of the destination hospital

Method of measurement

Pulse oximetry

Intervention groups**1****Description**

Intervention group: In order to prevent hypothermia for patients, a rescue blanket is used in ambulance during the transfer from the scene to the destination hospital.

Category

Prevention

2**Description**

Control group: In order to prevent hypothermia for patients, a conventional blanket is used in ambulance during the transfer from the scene to the destination hospital.

Category

Prevention

Recruitment centers**1****Recruitment center****Name of recruitment center**

Tehran Emergency Medical Center

Full name of responsible person

Parisa Hasani

Street address

No 86, Khalilabadi Boulevard, Sattari highway

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Province

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Email

parisahasaniems@gmail.com

Web page address

<http://umsha.ac.ir/includes/plink.aspx?linkid=62>

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tehran Emergency Medical Service

Full name of responsible person

Peyman Saberian

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No 86, Khalilabadi Boulevard, Sattari Highway

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peymansaberian61@gmail.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tehran Emergency Medical Service

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**

Other

Person responsible for general inquiries**Contact****Name of organization / entity**

Tehran Emergency Medical Service Center

Full name of responsible person

Parisa Hasani

Position

Head of Research Department

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

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Tehran University of Medical Sciences
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Person responsible for updating data

Contact

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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

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

The raw data and coded information of the patients participating in the study can be provided.

When the data will become available and for how long

There is no specific time period.

To whom data/document is available

Persons with academic position

Under which criteria data/document could be used

In order to design and conduct future studies in this field

From where data/document is obtainable

Contact with email of parisahasaniems@gmail.com

What processes are involved for a request to access data/document

After confirmation of the applicant's identity, we will contact him/her by email.

Comments