

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluating Family Presence Influencing Nosocomial Infections in Burn Intensive Care Unit

Protocol summary

Summary

The aim of this randomized clinical trial is evaluating family presence influencing nosocomial infections in Burn Intensive Care Unit. burn intensive care unit is Zareh hospital in Sari. Inclusion Criteria: all alert patients over 18 yrs, with their hospitalization passing 48 h and about the patient's attendant, being over 18 yrs and the attendant not suffering from communicable diseases through Eireborn (measles, chicken pox and etc.). Exclusion Criteria: the incidence of cases such as addiction, respiratory distress, intubation, the wound changing color toward getting infected, the patient's discharge or death and for the attendants ,not cooperating about the ward regulations and infection control precautions and afflicted with any communicable disease during the project implementation (especially via Eireborn). Sample: 360 patients being randomly selected and put in one of the test and control groups (each with 180 subjects). In the 3rd reception day, some training is presented by the researcher encompassing the ward regulations, infection control standard precautions in particular washing hands, as the most critical method to control nosocomial infection and preventing the spread of antimicrobial resistance .In the test group, the patient's desired attendant's 1 h presence is implemented in clinic for 5 consecutive days observing the trained cases from the 4th to the 8th days .In the control group , no presence of the attendant (the ward routine)is implemented .Nosocomial infection level in the patients is recorded from the 5th to the 15th ICU hospitalization days and in case of the patient being transferred to another ward from the ICU ,it is recorded for 7 days. The data on nosocomial infection symptoms and signs are collected using Nosocomial National Infection System (NNIS) designed questionnaire for the major nosocomial infections diagnosis (pneumonia, UTI, intravenous catheters, surgical site infection and burn) from the 4th to the 15th days and if the patient is eligible for one of the standard criteria for each of the main

infections, the related diagnostic code is extracted from NNIS table and recorded. All drugs (albumin and crystalloid), antibiotics, tests, cultures result (blood, urine, sputum, central catheters) and their antibiograms and surgery times during the project are recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201606297494N19**

Registration date: **2016-09-12, 1395/06/22**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-09-12, 1395/06/22

Registrant information

Name

Masoumeh Bagheri Nesami

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 3336 7551

Email address

mbagheri@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mazandaran University of Medical Sciences

Expected recruitment start date

2016-07-15, 1395/04/25

Expected recruitment end date

2017-07-16, 1396/04/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating Family Presence Influencing Nosocomial Infections in Burn Intensive Care Unit

Public title

Evaluating Family Presence Influencing Nosocomial Infections in Burn Intensive Care Unit

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion Criteria: all alert patients over 18 yrs, with their hospitalization passing 48 h and about the patient's attendant, being over 18 yrs and the attendant not suffering from communicable diseases through Eireborn (measles, chicken pox and etc.). Exclusion Criteria: the incidence of cases such as addiction, respiratory distress, intubation, the wound changing color toward getting infected, the patient's discharge or death and for the attendants ,not cooperating about the ward regulations and infection control precautions and afflicted with any communicable disease during the project implementation (especially via Eireborn).

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **360****Randomization (investigator's opinion)**

N/A

Randomization description**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**

Mazandaran University of Medical Sciences

Street address

Start of valiye asr highway, Imam Square, Sari, Mazandaran

City

Sari

Postal code

4736131167

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

IR.MAZUMS.REC.95.2368

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

Burns and corrosions

ICD-10 code

B99

ICD-10 code description

Other and unspecified infectious diseases

Primary outcomes**1****Description**

Ponumony

Timepoint

At the 4th and 15th day of admission

Method of measurement

by using a questionnaire designed by the national system of hospital infection surveillance

2**Description**

Burn wound infection

Timepoint

At the 4th and 15th day of admission

Method of measurement

by using a questionnaire designed by the national system of hospital infection surveillance

3**Description**

Sepsis

Timepoint

At the 4th and 15th day of admission

Method of measurement

by using a questionnaire designed by the national system of hospital infection surveillance

4**Description**

Catheter Related Blood stream Infections

Timepoint

At the 4th and 15th day of admission

Method of measurement

by using a questionnaire designed by the national system of hospital infection surveillance

Secondary outcomes

empty

Intervention groups

1

Description

the fourth day of hospitalization, one of a family member (patient preference) for five days in one-hour sessions before dressing change will be present at the bedside

Category

Other

2

Description

Control group (without family) are treated routine

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Zare hospital

Full name of responsible person

Masoomah Koohi

Street address

Zare Hospital,sari

City

Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research Mazandaran University of Medical Sciences.

Full name of responsible person

Dr.Ahmadali Enayati

Street address

Moallem Square-sari

City

Sari

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 Mazandaran 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

Mazandaran University of Medical Sciences

Full name of responsible person

Masoomah Koohi

Position

MSC in Critical Care Nursing

Other areas of specialty/work

Street address

Nasibeh School of Nursing and Midwifery, , Sari

City

Sari

Postal code

Phone

+98 11 3336 7342

Fax

Email

m.koohi61@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr Masoumeh Bagheri Nesami-Dr mohamad sadegh rezaii

Position

PHD in nursing/ faculty member-Professor of Pediatric Infectious (Associate Professor) Associate

Other areas of specialty/work

Street address

Mazandaran University of Medical Sciences

City

Sari

Postal code

48197-53171

Phone

+98 11 3336 7342

Fax

Email

anna30432003@yahoo.com

Web page address

Person responsible for updating data

Contact

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