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 Unitburn 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

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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
Masoomeh 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
Masoomeh Koohi
Position
MSC in Critical Care Nursing
Other areas of specialty/work
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Person responsible for scientific inquiries

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Dr Masoumeh Bagheri Nesami-Dr mohamad sadegh rezaii
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48197-53171
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Email
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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