

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

The impact of nurse's follow up care on burn patients' health

Protocol summary

Summary

The aim of this experiment is to determine the effect of nurse follow up care on burn patients' health. Design of study is RCT with control and intervention groups. Sampling will be purposive and based on inclusion criteria. Random allocation of subjects to control and intervention groups will be based on block randomization at discharge time. So that 6 block of size 4 will be prepared: AABB, ABAB, ABBA, BBAA, BABA, BAAB. Then these blocks will be arranged randomly and subjects will be allocated to two groups based on A and B. This will be repeated continuously. Sample size will be 90 (45 for intervention and 45 for control groups). Intervention group will receive the follow up care (home visit and telephone follow up). If any kind of problem recognizes, the patient will be referred to specialists (surgeon, psychologist, physiotherapist...). Also they will receive education and for prevention of contracture, goniometry will be done for them and ROM exercise will be educated. Control group will receive routine care in burn unit. The duration of follow up care is 6 months. Both control and intervention groups will be assessed at discharge time, 1.5, 3 and 6 months later. At sixth month the health status of both groups will be assessed and compared.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2016110630712N2**
Registration date: **2017-04-14, 1396/01/25**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-04-14, 1396/01/25

Registrant information

Name

Nastaran Heydarikhayat

Name of organization / entity

Shahid Beheshti University of Medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 23871

Email address

heydarikh@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2016-07-22, 1395/05/01

Expected recruitment end date

2017-07-23, 1396/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The impact of nurse's follow up care on burn patients' health

Public title

The impact of nurse's follow up care on health status of burn patients

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria: Age>18 years; severity of burn > 15%; second and third degree burn; orientation to person, place and time for answering to questions. Exclusion criteria : No willing to continue the study; past history of admission to burn centers; history of visual and hearing

disorder or mental retardation; history of depression and schizophrenia.

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Shahid Beheshti University of Medical Sciences,
Shahid Arabi Avenue, Yemen Avenue, Shahid
Chamran highway, Tehran

City

Tehran

Postal code

Approval date

2015-11-03, 1394/08/12

Ethics committee reference number

SBMU2.REC.1394.168

Health conditions studied

1

Description of health condition studied

burn

ICD-10 code

T20-T32

ICD-10 code description

Incl.: burns (thermal) from: electrical heating appliances
electricity flame friction hot air and hot gases hot objects
lightning radiation chemical burns [corrosions]
(external)(internal) scalds Excl.: erythema [dermatitis] ab

igne (L59.0) radiation-rela

Primary outcomes

1

Description

Health status

Timepoint

3th and 6th month after discharge

Method of measurement

Burn Specific Health Scale, brief- The Persian version of this tool has 40 questions and 8 dimensions. Dimensions describe patients performance such as sensitivity to heat, hand's performance and simple abilities, therapeutic regimes, labor, sexual functioning, interpersonal relationships, emotion and body image. Items will be scored based on a 5- degree likert, 0 (severly) to 4 (no/ not at all) and higher scores mean higher performance and quality of life.

Secondary outcomes

1

Description

Psychological Assessment

Timepoint

Discharge time, 1.5, 3 and 6 months after discharge

Method of measurement

General Health Questionnaire 28 (GHQ-28)

2

Description

Pain

Timepoint

Discharge time, 1.5, 3 and 6 months after discharge

Method of measurement

Brief Pain Inventory

3

Description

Pruritus/ Itching

Timepoint

Discharge time, 1.5, 3 and 6 months after discharge

Method of measurement

VAS

4

Description

Scar

Timepoint

Discharge time, 1.5, 3 and 6 months after discharge

Method of measurement

VSS: Vancouver Scar Scale

5

Description

Range Of Motion: ROM

Timepoint

Discharge time, 1.5, 3 and 6 months after discharge

Method of measurement

Goniometry

Intervention groups

1

Description

Intervention group: 1. Oral or written education or education by telephone about wound care, skin graft, donor care. 2-home visit at least 3 times or based on patients' needs. 3-phone call based on patients' needs. The number of phone calls are more during first weeks after discharge from hospital and decrease gradually. 4. goniometry and determination the range of motion and refer to surgeon and physiotherapist if needed.5-problem detection and refer to specialists.

Category

Other

2

Description

Control group: routine of hospital care that always deliver by nurses and doctors.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital in Kermanshah

Full name of responsible person

Nastaran Heydarikhayat

Street address

Imam Khomeini Hospital, Naghlieh Ave, Kermanshah

City

Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Afshin Zarghi

Street address

Shahid Beheshti University of Medical Sciences, Shahid Arabi Avenue, Yemen Avenue, Shahid Chamran highway, Tehran

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 of Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Nastaran Heydarikhayat

Position

PhD student in nursing

Other areas of specialty/work

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Person responsible for updating data

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Cross Road, Niayesh highway, Tehran, Iran
City

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