Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of hypnotherapy on intensity and quality of background pain and pain anxiety of men with second and third degree burn injuries: A blinded, randomized clinical trial with control group

Protocol summary

Summary

Present study has been designed to evaluate the effect of hypnotherapy on intensity and quality of background pain and pain anxiety of second and third degree male burn patients. Sixty male patients of Imam Khomeini Teaching Hospital of Urmia will be allocated to experimental and placebo control group (thirty participants for any group). Minimization will be utilized for allocation as a method of randomization.Minimization is a method of randomization that allocates subjects to the treatment group that best maintains balance in stratifying factors. It is effective even at small sample sizes and with multiple stratification variables.First participant will be allocated randomly to one of the groups and next patients depending on the main variables of the study, will be placed in a group which has less people with considered variable in it. For experimental group, four hypnotherapy sessions with pain and anxiety reduction suggestions will be done. In control group,four hypnotherapy sessions without pain and pain anxiety reduction suggestions (neutral hypnosis) will be done. All intervention will be done on afternoon. Patients would not be aware of group allocation and in which group they are (blinding). Main inclusion criteria are: degree two and three burn injury; total body surface area ranging from 5 to 40 percent and having no diagnosis of epilepsy. Before intervention, after second and forth session of hypnosis, all variables will be evaluated by someone who is not aware of allocation of groups (blinding). Data analyzer again would not be aware of groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016100830214N1**

Registration date: **2016-11-11, 1395/08/21**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-11-11, 1395/08/21

Registrant information

Name

Hossein Jafarizadeh

Name of organization / entity

Urmia University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Research Vice- President of Urmia University of Medical Sciences

Expected recruitment start date

2016-10-31, 1395/08/10

Expected recruitment end date

2016-12-20, 1395/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of hypnotherapy on intensity and quality of

background pain and pain anxiety of men with second and third degree burn injuries: A blinded, randomized clinical trial with control group

Public title
Effect of hypnotherapy on background pain and pain anxiety of men with burn injuries hospitalized in burn ward
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: patients should have diagnosis of burn injury and be hospitalized in hospital; men who are between 18 and 50 years old; passing the emergency phase of burn and being in later phases; second and third degree burn injuries with total body surface area ranging from 5 to 40 percent; Farsi and Azeri speakers; having no problem in hearing and vision; having no diagnosis of psychosis, epilepsy, drug abuse or mental problems; having no history of hypertension or diabetes. Exclusion criteria: unwillingness of participation in research; leaving the ward for any reason such as transferring to other hospitals or intensive care unit; discharge or death; wound infection with positive culture; having any out of routine procedure.
Age
From **18 years** old to **50 years** old
Gender
Male

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Board of Urmia University of Medical Scienses
Street address
Urmia University of Medical Scienses, Emergency Alley,Resalat blvd, Urmia
City
Urmia
Postal code
Approval date
2016-04-06, 1395/01/18
Ethics committee reference number
IR.rec.umsu.1395.3

Health conditions studied

1

Description of health condition studied
Burn of second degree
ICD-10 code
T30.2
ICD-10 code description
Burn of second degree, body region unspecified

2

Description of health condition studied
Burn of third degree
ICD-10 code
T30.3
ICD-10 code description
Burn of third degree, body region unspecified

Primary outcomes

1

Description
Intensity of pain
Timepoint
Before intervention, after second and also forth session of intervention
Method of measurement
Visual analogue scale

Secondary outcomes

1

Description
Quality of pain
Timepoint
Before intervention, after second and forth session
Method of measurement
Short form of McGill pain questionnaire

2

Description
Pain Anxiety
Timepoint
Before intervention, after second and forth session
Method of measurement
Burn Specific Pain Anxiety Scale

Intervention groups

1

Description

Control group: In this group four sessions of hypnosis will be done. Needed time for hypnosis sessions will range from 15 minutes to one hour depending on the hypnotizability. Different induction techniques would be utilized depending on the age and personal traits. In induction phase of hypnosis some techniques such as eye fixation, progressive muscle relaxation and hand levitation will be used. Imagination, reverse counting, dissociation and progressive muscle relaxation are among the techniques which will be used for deepening of the trance. Non therapeutic and unspecified suggestions will be utilized in this group as placebo control. All sessions will be done between 16 and 20 PM that patients are not tiered. An appropriate room with suitable light and temperature will be chosen for hypnosis sessions.

Category

Treatment - Other

2

Description

Intervention group: In this group four sessions of hypnosis will be done. Needed time for hypnosis sessions will range from 15 minutes to one hour depending on the hypnotizability. Different induction techniques would be utilized depending on the age and personal traits. In induction phase of hypnosis some techniques such as eye fixation, progressive muscle relaxation and hand levitation will be used. Imagination, reverse counting, dissociation and progressive muscle relaxation are among the techniques which will be used for deepening of the trance. Therapeutic suggestions will be utilized for disappearing the pain and anxiety. All sessions will be done between 16 and 20 PM that patients are not tiered. An appropriate room with suitable light and temperature will be chosen for hypnosis sessions.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Teaching Hospital of Urmia

Full name of responsible person

Fardin Ajoudani

Street address

Imam Khomeini Teaching Hospital, Ershad avenue, Urmia

City

Urmia

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Vice President of Urmia University of Medical Sciences

Full name of responsible person

Dr. Iraj Mohebbi

Street address

Research Vice President of Urmia University of Medical Sciences, Emergency alley, Resalat blvd, Urmia

City

Urmia

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Research Vice President of Urmia 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

Urmia University of Medical Sciences

Full name of responsible person

Hossein Jafarizadeh

Position

Master of Science in Nursing, Head of Community Health Nursing Department

Other areas of specialty/work

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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