Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Jun 2026

Comparison of the effects of family-centered affective stimulation and sensory stimulation on narcotic poisoning comatose patients' level of consciousness and cortex activity

Protocol summary

Study aim
Determinate of the effect of family-centered affective stimulation on narcotic poisoning patients' level of consciousness and cortex activity

Design
Randomised, and parallel group trial with blinded the participants and outcome assessment. Randomisation are centralised with an allocation protocol will developed using the permutated block randomization technique.

Settings and conduct
This study is designed and performed following two previous studies purely with clinical evaluation. This study are a three-group double-blind randomized controlled trial. Nurses and technician who measured patients' LOC and EEG are blind to the study. The study setting has some ICU of a teaching hospital (Loghman) of Shahib Beheshti Medical Sciences University located in Tehran, Iran.

Participants/Inclusion and exclusion criteria
The affliction by opium poisoning a GCS=5–8, and an age of 18–65. Patients who are discharged from the ICU, died, or needed an emergency therapeutic intervention, other poisoning in addition to narcotic drugs, stroke or other cerebral events, ... are excluded.

Intervention groups
The study groups consisted of three groups. Intervention group: family-centered affective stimulation. In this group, a close family member (father, mother, spouse, child, sister, or brother) who had the strongest emotional relationship with the intended patient are selected based on the recommendations of the other members of the family. Placebo group: A fixed trained person who unfamiliar to all patients in the placebo group are provided them pure sensory (auditory, tactile, and kinetic) stimulation. Control group: Patients in the control group would not receive any of the above mentioned sensory or affective stimulation. Rather, they just receive care services and sensory stimulation which routinely.

Main outcome variables
level of consciousness and cortex activity

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180930041185N2**
Registration date: **2019-10-01, 1398/07/09**
Registration timing: **prospective**

Last update: **2019-10-01, 1398/07/09**
Update count: **0**

Registration date
2019-10-01, 1398/07/09

Registrant information

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Name of organization / entity
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-10-23, 1398/08/01

Expected recruitment end date
2020-10-22, 1399/08/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effects of family-centered affective stimulation and sensory stimulation on narcotic poisoning comatose patients' level of consciousness and cortex activity

Public title
The effects of family-centered affective stimulation on narcotic poisoning comatose patients' level of consciousness and cortex activity
Purpose
Basic scienece
Inclusion/Exclusion criteria
Inclusion criteria:
Affliction by opium poisoning A Glasgow Coma Scale (GCS) score of 5–8 Age of 18–65 year
Exclusion criteria:
Patients who discharged from the ICU Death for any reason Needed an emergency therapeutic intervention Other poisoning in addition to narcotic drugs Stroke or other cerebral events History of CVA and drug abuse Use of psychiatric drugs during the study
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
Initially, an allocation protocol will developed using the permutated block randomization technique (Pocock, 2013). Then, eligible patients will consecutively recruited and randomly allocated to an experimental, a placebo, or a control group based on the permuted block randomization protocol. Allocation numbers will generated using a table of random numbers.
Blinding (investigator's opinion)
Double blinded
Blinding description
Patients in coma are unaware of the type of intervention and their allocation in the intervention, placebo or control groups. Research colleagues, who record GCS and EEG, are unaware of patients' placement and allocation in study groups.
Placebo
Used
Assignment
Parallel
Other design features
This study was designed to carry out two studies (with the guidance of the principle investigator) with a purely clinical design. In this study, in addition to the design and clinical evaluation of the intervention, the pathway and mechanism of impact on brain cortical activity are also analyzed using EEG. For this reason basic science was chosen. This concurrent characteristic has not been observed in any of the previous studies by the principle investigator or other similar studies in Iran and the world. The project has also been approved and registered at the National Institute for Medical Research Development (NIMAD) No. 983043.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
این طرح همراه پروپوزال اخلاق پژوهش در موسسه ملی تحقیقات علوم پزشکی (نیماد) تصویب و ثبت گردید.
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Approval date
2019-07-30, 1398/05/08
Ethics committee reference number
IR.NIMAD.REC.1398.168

Health conditions studied

1

Description of health condition studied
Coma caused by opium poisoning
ICD-10 code
(S00-T98)
ICD-10 code description
injury, poisoning and certain other consequences of external causes

Primary outcomes

1

Description
The score of consciousness level is measured by the GCS scale and patients are selected with a score of 5 to 8. Post-intervention level of consciousness score can range from 3 to 15 which is measured and recorded by the research fellow nurses.

Timepoint
Twice a day (morning and evening) up to 7 days
Method of measurement
Before and after intervention by a fellow nurse

2

Description
Cortical activity recorded by EEG is interpreted and analyzed by a neurologist.EEG signals will be recorded with a digital 26-channel scalp EEG device (g.tec, Guger Technologies, Graz, Austria), using the international 10-20 system. The EEG data will be acquired with a linked ear reference, sampled at 256 Hz with filter between 0.1Hz and 40Hz.
Timepoint
Once a day every 7 days
Method of measurement
Every day before and after the intervention (morning shift) every 7 days

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Intervention 1 in the experimental group: family-centered affective stimulation In the experimental group, a close family member (father, mother, spouse, child, sister, or brother) who had the strongest emotional relationship with the intended patient are selected based on the recommendations of the other members of the family. In parallel, two critical care nurses are provided with training about sensory-affective stimulation, ward rules and regulations, and the importance of family members' scheduled attendance at their patients' bedside. In ICU admission, either of these two nurses are provided the intended patient's close family member with training about family-centered affective stimulation.Training is about the rules and regulations of ICU, patient's condition, the necessity and importance of scheduled attendance at patient's bedside, hand washing before entering and after leaving ICU, how to establish the relationship with the patient, and how to provide sensory-affective stimulation. The selected family members attended their patients' bedside and provided family-centered affective stimulation twice a day (at 11:00 and 15:00) for seven consecutive days (fourteen times in total). The length of each session was 30–45 min.During the sessions, the in-charge nurse of the intended patient accompanied the family member in order to ensure the accurate implementation of the intervention and to help and support the family member. At the first session, either of the two trained nurses provided the intended family member with training about the family-centered affective stimulation program and personally implemented the program.Family-centered affective stimulation consisting of sensory-affective stimulation Family-centered affective stimulation is a sensory-affective stimulation program which consist of four main steps as follows. Auditory stimulation for twenty minutes: In this step, the family member gently will be introduced himself/herself to the patient and will call patient's name for several times. Then, he/she will provided the patient with information about time and place. After that, he/she are talked with the patient for fifteen minutes about happy daily events in the family, pleasant shared memories, and the health status of family members. Sensory stimulation for ten minutes: The family member firmly will be held the patient's hands and care his/her face and body.Kinetic stimulation for fifteen minutes: In this step, the family member will be massaged the patient's hands and legs and are performed passive range-of-motion activities for several times under the in-charge nurse's supervision. Moreover, he/she will change the patient's position and massage his/her back with the help of the nurse. Affective conversation: During his/her attendance at the patient's bedside, the family member are speak with the patient about patient's interests, enjoyable experiences, and other family members' health status and interests.
Category
Rehabilitation

2

Description
Intervention group 2: Intervention in the placebo group: A fixed trained person who unfamiliar to all patients in the placebo group will be provided them with 30–45 min pure sensory (auditory, tactile, and kinetic) stimulation twice a day for seven consecutive days as follows: introduction (two minutes); providing information about time and place (three minutes); talking about care services, treatments, and patients' health status compared with previous days (ten minutes); performing nursing measures such as hemodynamic measurements or vital signs assessments (ten minutes); touching patients, moving their extremities, and changing their positions (twenty minutes).
Category
Rehabilitation

3

Description
Control group: Intervention in the control group; Patients in the control group are not receive any of the above mentioned sensory or affective stimulation. Rather, they just receive care services and sensory stimulation which routinely will be provided to all patients in the study setting. These services and stimulation include normal lighting of the ICU, noises of the equipment, medication administration, and physical care services such as back and limb massage by nurses, physical therapists, and nurse assistants. These services also will provide to the patients in the placebo and the experimental groups. Patient-family visitation in the control group is also are performed according to the routine of the setting and through the ICU windows.
Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Loghman hospital

Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

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Full name of responsible person
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Web page address

Grant name
The elite grant

Grant code / Reference number

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

Title of funding source
National Institute of Medical Research Development (NIMAD)

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
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Full name of responsible person
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Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
لزومی ندارد در خصوص بخشی از این داده های بصورت داده های دموگرافیک که برای تفسیر یافته ها مهم است در مقاله خواهد آمد.

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable