

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Aromatherapy with orange perfume on pain, anxiety and vital signs of patients with limbs fracture

Protocol summary

Summary

Abstract: The goal of this study is determining of the effect of aromatherapy with orange perfume on pain, anxiety and vital signs of patients with limbs fracture hospitalized in emergency ward. Inclusion Criteria: Age above 18; Intact visual and smell senses. Exclusion Criteria: No tendency for continuing the study; Transfer to other wards. 100 patients with limbs fractures selected conveniently. Then based on blocking randomized method, allocated into two intervention and control groups. This study will be accomplished during a shift (morning or evening). In intervention group besides doctor's order, 4 drops of orange perfume is poured on a pad and then it connected to the patient's collar with a distance of 20 centimeter. Every 1 hour the old pad replaced by new one. Then every 1 hour (up to 6 h.) the patient's pain level and vital signs will be measured. The patient's anxiety level will be measured only before and after intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201607124519N6**

Registration date: **2016-07-30, 1395/05/09**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-07-30, 1395/05/09

Registrant information

Name

Davood Hekmatpou

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Arak University of Medical Sciences

Expected recruitment start date

2016-07-10, 1395/04/20

Expected recruitment end date

2016-10-11, 1395/07/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Aromatherapy with orange perfume on pain, anxiety and vital signs of patients with limbs fracture

Public title

The effect of aromatherapy with orange perfume on pain, anxiety and vital signs of patients with limbs fracture hospitalized in Emergency Ward

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion Criteria: Age above 18; Intact visual and smell senses. Exclusion Criteria: No tendency for continuing the study; Transfer to other wards.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

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

Medical Ethics Committee of Arak University of
Medical Sciences

Street address

Payambare Azam Complex, Sardasht

City

Arak

Postal code

Approval date

2016-07-03, 1395/04/13

Ethics committee reference number

IR.ARAKMU.REC.1395.111

Health conditions studied

1

Description of health condition studied

Limb Fracture

ICD-10 code

T02.6

ICD-10 code description

Fractures involving multiple regions of upper limb(s) with
lower limb(s)

Primary outcomes

1

Description

Pain

Timepoint

Every 1 hour

Method of measurement

Visual Analogue Scale

2

Description

Vital Signs

Timepoint

Every 1 hour

Method of measurement

Blood pressure apparatus

Secondary outcomes

1

Description

Anxiety

Timepoint

Before and After intervention

Method of measurement

Speilberger State Anxiety Inventory

Intervention groups

1

Description

Intervention Group: In intervention group besides
doctor's order, 4 drops of orange perfume is poured on a
pad and then it connected to the patient's collar with a
distance of 20 centimeter. Every 1 hour the old pad
replaced by new one. Then every 1 hour (up to 6 h.) the
patient's pain level and vital signs will be measured. The
patient's anxiety level will be measured only before and
after intervention.

Category

Other

2

Description

Control Group: Control group: Only doctor's orders for
relieving the patient's pain and anxiety level will be
accomplished. Then every 1 hour (up to 6 h.) the
patient's pain level and vital signs will be measured. The
patient's anxiety level will be measured only before and
after intervention.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Valie Asr Hospital

Full name of responsible person

Dr. Hekmatpou

Street address

City

Arak

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor Of Research, Arak University of
Medical Sciences

Full name of responsible person

Dr. Rafiei

Street address

Payambare Azam Complex, Sardasht

City

Arak

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice chancellor Of Research, Arak 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**

Arak University of Medical Sciences

Full name of responsible person

Dr. Hekmatpou

Position

Faculty Member

Other areas of specialty/work**Street address**

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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