

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Comparison Effect of Matricaria chamomilla and Trachyspermum Copticum on Withdrawal Syndrome in Narcotics Anonymous

Protocol summary

Summary

purpose: Comparison Effect of Matricaria chamomilla and Trachyspermum copticum on Withdrawal syndrome in Narcotics Anonymous. Study design: triple blind clinical trial with a control group. Inclusion criteria were: age between 18 to 100 years, having opium addiction, man Exclusion criteria: known underlying disease (physical and mental); Mental retardation; taking other pain medication or herbs in order to reduce symptoms, patients taking methadone, having allergy to drug plants Sample size: 135 Interventions studied: after sampling, Samples with randomization divided in 2 case and control group. Intervention group 1: will take Matricaria chamomilla (oral drops) 3cc (TDS) one hours post parandial and intervention group 2 patients will receive Trachyspermum copticum (oral drops) similar.control group Controls the amount of Clonidine tablets daily 2 mg is given Intervention time: two months Primary outcome: reduction of the uncomfortable symptoms of drug addiction. Data collection Instrument: Questionnaire symptoms of opiate withdrawal syndrome.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201309053227N4**

Registration date: **2015-08-19, 1394/05/28**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-08-19, 1394/05/28

Registrant information

Name

Ashraf Salehi

Name of organization / entity

Arak University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Arak University of Medical Sciences

Expected recruitment start date

2013-08-23, 1392/06/01

Expected recruitment end date

2014-01-21, 1392/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison Effect of Matricaria chamomilla and Trachyspermum Copticum on Withdrawal Syndrome in Narcotics Anonymous

Public title

Effect of Matricaria chamomilla and Trachyspermum Copticum on Addiction

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age between 18 to 100 years, having opium addiction, man. Exclusion criteria: known underlying disease (physical and mental); Mental retardation; taking other pain medication or herbs in order to reduce symptoms, patients taking methadone, having allergy to drug plants

Age
From **18 years** old to **100 years** old
Gender
Male

Phase
2
Groups that have been masked
No information

Sample size
Target sample size: **135**
Randomization (investigator's opinion)
Randomized

Randomization description
Blinding (investigator's opinion)
Triple blinded

Blinding description
Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Arak University of Medical Sciences
Street address
Iran-arak-Arak University of Medical Sciences
City
Arak
Postal code
Approval date
2013-08-23, 1392/06/01
Ethics committee reference number
5-150-92

Health conditions studied

1

Description of health condition studied
Opium Addiction
ICD-10 code
F11
ICD-10 code description
Mental and behavioural disorders due to use of opioids

Primary outcomes

1

Description
Resting Pulse Rate
Timepoint

2,5,12,19,26 days
Method of measurement
clinical opiate withdrawal scale

2

Description
GI Upset
Timepoint
2,5,12,19,26 days
Method of measurement
clinical opiate withdrawal scale

3

Description
Sweating
Timepoint
2,5,12,19,26 days
Method of measurement
clinical opiate withdrawal scale

4

Description
Tremor
Timepoint
2,5,12,19,26 days
Method of measurement
clinical opiate withdrawal scale

5

Description
Restlessness
Timepoint
2,5,12,19,26 days
Method of measurement
clinical opiate withdrawal scale

6

Description
yawning
Timepoint
2,5,12,19,26 days
Method of measurement
clinical opiate withdrawal scale

7

Description
pupil size
Timepoint
2,5,12,19,26 days
Method of measurement
clinical opiate withdrawal scale

8

Description
anxiety or irritability
Timepoint
2,5,12,19,26 days

Method of measurement

clinical opiate withdrawal scale

9**Description**

bone or joint aches

Timepoint

2,5,12,19,26 days

Method of measurement

clinical opiate withdrawal scale

10**Description**

gooseflesh skin

Timepoint

2,5,12,19,26 days

Method of measurement

clinical opiate withdrawal scale

11**Description**

runny nose or tearing

Timepoint

2,5,12,19,26 days

Method of measurement

clinical opiate withdrawal scale

Secondary outcomes**1****Description**

-

Timepoint

-

Method of measurement

-

Intervention groups**1****Description**

Intervention group 1: will take Matricaria chamomilla 20% (oral drops)3cc, TDS, one hours post parandial for one month

Category

Treatment - Drugs

2**Description**

in intervention group 2 patients will receive Trachyspermum copticum10%(oral drops), 3cc, TDS for one month

Category

Treatment - Drugs

3**Description**

In control group will take tab clonidin 2 mg per day with in a period one month.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Narcotics Anonymous Camps khomein City

Full name of responsible person

Hamid Momeni

Street address

Arak University Of Medical Science

City

khomein

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

Mohammad Rafiei

Street address

Arak University of Medical Sciences

City

Arak, Shahid Shiroudi, Alamolhoda, University of Medical Sciences

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

Yes

Title of funding source

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 Science

Full name of responsible person

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Position

Academic Member Of khomain-college of Medical Science

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Web page address**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