Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Rosemarinus officinalis effects on decreasing opium withdrawal syndrome

Protocol summary

Summary

The purpose of this study was to investigate the effect of Rosemary plant in reducing undesirable symptoms of opium withdrawal syndrome. In this double blind controlled trial, 80 opium addicted persons who are candidates of leaving addiction were assigned in the intervention or control group to receive methadone & rosemary or methadone & placebo for two weeks, retrospectively. Withdrawal signs and symptoms were measured 3, 7, and 14 days after the intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138903054033N1**
Registration date: **2010-04-21, 1389/02/01**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2010-04-21, 1389/02/01

Registrant information

Name

Hasan Solhi

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 86 1222 1041

Email address

solhi2@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Barij essence pharmaceutical co and Arak University of Medical Sciences

Expected recruitment start date

2010-04-21, 1389/02/01

Expected recruitment end date

2010-07-11, 1389/04/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Rosemarinus officinalis effects on decreasing opium withdrawal syndrome

Public title

Rosemary effects in leaving addiction

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age 20-60 years, opium consumption less than 2.3g daily, more than a year opium consumption, Exclusion criteria: known hypersensitivity to rosemary plant, previous history of psychological disorders, incidence of side effects, opium consumption during the study

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded
Blinding description
Placebo
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
Faculty of Medicine, University campus, Sardasht St., Arak
City
Arak
Postal code
Approval date
empty
Ethics committee reference number
88-71-2

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
heart rate
Timepoint
day before and day 3,7,14 after intervention
Method of measurement
physical exam

2

Description
perspiration
Timepoint
day 3,7,14 after intervention
Method of measurement
opium withdrawal questionnaire

3

Description
pupil size
Timepoint
day 3,7,14 after intervention
Method of measurement
physical exam

4

Description
sialorrhea
Timepoint
day 3,7,14 after intervention
Method of measurement
opium withdrawal questionnaire

5

Description
yawn
Timepoint
day 3,7,14 after intervention
Method of measurement
opium withdrawal questionnaire

6

Description
respiratory rate
Timepoint
day before and day 3,7,14 after intervention
Method of measurement
physical exam

7

Description
sneezing
Timepoint
day 3,7,14 after intervention
Method of measurement
visual analogue scale

8

Description
nausea
Timepoint
day 3,7,14 after intervention
Method of measurement
visual analogue scale

9

Description
vomiting
Timepoint
day 3,7,14 after intervention
Method of measurement
opium withdrawal questionnaire

10

Description
defication
Timepoint
day before and day 3,7,14 after intervention
Method of measurement
opium withdrawal questionnaire

11

Description
insomnia
Timepoint
day 3,7,14 after intervention
Method of measurement
opium withdrawal questionnaire

12

Description
sleep duration in a day
Timepoint
day 3,7,14 after intervention
Method of measurement
opium withdrawal questionnaire

13

Description
muscle jerking
Timepoint
day 3,7,14 after intervention
Method of measurement
visual analogue scale

14

Description
muscle pain
Timepoint
day 3,7,14 after intervention
Method of measurement
visual analogue scale

15

Description
deep tendon reflex
Timepoint
day 3,7,14 after intervention
Method of measurement
physical exam

16

Description
change body temprature feeling
Timepoint
day 3,7,14 after intervention
Method of measurement
visual analogue scale

17

Description
craving
Timepoint
day 3,7,14 after intervention
Method of measurement
visual analogue scale

18

Description
epiphora
Timepoint
day 3,7,14 after intervention
Method of measurement
opium withdrawal questionnaire

19

Description
rhinorroea
Timepoint
day 3,7,14 after intervention
Method of measurement
opium withdrawal questionnaire

20

Description
Social/occupational dysfunction
Timepoint
day 3,7,14 after intervention
Method of measurement
opium withdrawal questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Methadone 5mg tabs po 4 times a day for the first week & 3 times a day for the 2nd week plus placebo capsules
Category
Placebo

2

Description
Methadone 5mg tabs 4 times a day po for the 1st week & 3 times a day for the 2nd week plus Rosemary 300mg capsules, 16 capsules a day po for 3 days then 12 capsules daily for the following 4 days & then 8 capsules daily for the following 7 days
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Valiasr hospital
Full name of responsible person
Hassan Solhi, Forensic Sciences and poisoning specialists
Street address
Valiasr hospital, Valiasr square, Arak
City
Arak

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Hasan Solhi
Street address
Faculty of Medicine, University campus, Sardasht St., Arak
City
Arak
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 Sciences
Full name of responsible person
Hasan Solhi
Position
Forensic science and poisoning specialist
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Person responsible for updating data

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Email
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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