Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of Curcuma Longa on the chest pain, sleep quality and hemodynamic indices in patients with acute coronary syndrome

Protocol summary

Study aim
To determine the effect of Curcuma Longa on the chest pain, sleep quality and hemodynamic indices in patients with acute coronary syndrome

Design
Clinical Trial, by using block randomization, the Patients enter in intervention, placebo or control group, A pilot study including10 patients from each group, will determine the size of the sample, Parallel groups, double blind.

Settings and conduct
This study is performed in the intensive cardiac care unit of Kosar Hospital in Semnan. The medicine is given to the patient by the physician (double blind), the researcher and patient did not know about the Curcuma Longa and placebo.

Participants/Inclusion and exclusion criteria
Inclusion criteria: diagnosis acute coronary syndrome, patient consent for participation in the study, patient 45 to 75 years old, lack of active mental illness, mental retardation, deafness, blindness, lack of sensitivity to Curcuma Longa, lack of addiction to alcohol and Opioid, patients who are able to speak and understand language and conscious, no history of sleeping drugs consumption, chest pain score greater than four, systolic blood pressure 90-100 mmHg. Exclusion criteria: pregnant women, patients with gallstones or bile disorders.

Intervention groups
The intervention group received one 500 mg Curcuma Longa tablet once a day, 9 am after breakfast, for three days, in addition to routine regimen. The control group 1 group receives placebo tablet once a day, 9 am after breakfast, for three days, in addition to routine regimen. The control group 2 receives routine regimen.

Main outcome variables
Evaluation of pain is performed with Numeric Rating Scale; sleep quality by St Mary's Hospital Sleep Questionnaires; evaluation of hemodynamic indicators by the monitor of Pooyandegan Rah-e-Salamat

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20110427006318N14**
Registration date: **2020-10-22, 1399/08/01**
Registration timing: **prospective**

Last update: **2020-10-22, 1399/08/01**
Update count: **0**

Registration date
2020-10-22, 1399/08/01

Registrant information

Name
Monir Nobahar
Name of organization / entity
Semnan University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 23 3365 4190
Email address
Nobahar43@Yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-10-24, 1399/08/03

Expected recruitment end date
2021-04-23, 1400/02/03

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of Curcuma Longa on the chest pain, sleep quality and hemodynamic indices in patients with acute coronary syndrome

Public title
The effect of Curcuma Longa on the chest pain, sleep quality and hemodynamic indices in patients with acute coronary syndrome

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Diagnosis acute coronary syndrome Patient consent for participation in the study Patient 45 to 75 years old Lack of active mental illness, mental retardation, deafness, blindness Lack of sensitivity to Curcuma Longa Lack of addiction to alcohol and Opioid Patients who are able to speak and understand language and conscious No history of sleeping drugs consumption Chest pain score greater than four Systolic blood pressure 90-100 mmHg

Exclusion criteria:
Pregnant women Patients with gallstones or bile disorders

Age
From **45 years** old to **75 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **10**

Randomization (investigator's opinion)
Randomized

Randomization description
The research sample assigned to the groups of the study by permuted blocks randomization. The blocks will be (ABC, ACB, BAC, BCA, CAB, CBA), A is the intervention group, B is the control group 1 and C is the control group 2. After randomly selecting one of the six possible blocks, three consecutive samples are randomly placed in one of the groups (intervention, control 1 or control 2). Blocking is used within sex, randomization is done separately for men and women.

Blinding (investigator's opinion)
Double blinded

Blinding description
The medicine is given to the patient by the physician, so that the researcher and the patients participating in the study do not know about the type of intervention (Curcuma Longa, control 1 or control 2) and do not know who is in which group (double blind).

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Semnan University of Medical science

Street address
Semnan University of Medical Sciences, Basij Boulevard, Semnan

City
Semnan

Province
Semnan

Postal code
351313811

Approval date
2020-09-22, 1399/07/01

Ethics committee reference number
IR.SEMUMS.REC.1399.183

Health conditions studied

1

Description of health condition studied
Acute coronary syndrome

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Chest pain

Timepoint
Evaluation of pain is performed before and half an hour after the intervention for three consecutive days.

Method of measurement
Numeric Rating Scale

Secondary outcomes

1

Description
Sleep quality

Timepoint
Evaluation of sleep quality is performed before the intervention and three consecutive days.

Method of measurement
St Mary's Hospital Sleep Questionnaires

2

Description
Hemodynamic indicators
Timepoint
Evaluation of hemodynamic parameters is performed before and half an hour after the intervention for three consecutive days.
Method of measurement
Monitor of Pooyandegan Rah-e-Salamat

Intervention groups

1

Description
Intervention group: The intervention group received one 500 mg Curcuma Longa tablet once a day, 9 am after breakfast, for three days, in addition to routine regimen.
Category
Treatment - Other

2

Description
Control group: The control group 1 receives placebo tablet once a day, 9 am after breakfast, for three days, in addition to routine regimen.
Category
Placebo

3

Description
Control group: The control group 2 receives routine regimen.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Kosar hospital
Full name of responsible person
Monir Nobahar
Street address
Faculty Nursing and Midwifery, Semnan University of Medical Sciences
City
Semnan
Province
Semnan
Postal code
3513138111
Phone
+98 23 3365 4190
Fax
+98 23 3365 4209
Email
nobahar43@semums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Semnan University of Medical Sciences
Full name of responsible person
Parviz Kokhaei
Street address
Semnan University of Medical Sciences, Basij Boulevard, Semnan
City
Semnan
Province
Semnan
Postal code
3513138111
Phone
+98 23 3345 1336
Email
P_kokha@yahoo.com
Grant name
-
Grant code / Reference number
-
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Semnan University of Medical Sciences
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
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Semnan University of Medical Sciences
Full name of responsible person
Monir Nobahar
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Semnan University of Medical Sciences, Basij Boulevard, Semnan
City
Semnan
Province

Semnan

Postal code
3513138111

Phone
+98 23 3365 4190

Email
nobahar43@semums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Semnan University of Medical Sciences

Full name of responsible person
Monir Nobahar

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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Semnan University of Medical Sciences, Basij Boulevard, Semnan

City
Semnan

Province
Semnan

Postal code
3513138111

Phone
+98 23 3365 4190

Email
nobahar43@semums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Semnan University of Medical Sciences

Full name of responsible person
Monir Nobahar

Position
Associate professor

Latest degree
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Nursery

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Semnan University of Medical Sciences, Basij Boulevard, Semnan

City
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Province
Semnan

Postal code
3513138111

Phone
+98 23 3365 4190

Email
nobahar43@semums.ac.ir

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
Data is confidential

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

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

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available