

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effectiveness of heat and cold therapy on acute back pain in patients referred to Orthopaedic Clinic of Kashani hospital in Shahrekord

Protocol summary

Summary

The aim of this study is to determine the effect of both, warm and cold therapy on pain in patients with low back pain treatment. This study is a clinical trial. 87 men and women who are 20-50 years old with acute low back pain (pain that is less than one month) referred to the Ayatollah orthopedic clinic in the Kashan University of Medical Sciences with the convenience sampling method. Patients are divided randomly into three groups (warm, cold therapy, and control group). All three groups treated with Naproxen 500 mg tablets twice a day for one week. Group A: They treat with a warm water bag for 20 minutes twice daily in a week. Group B: They treat with ice for 20 minutes twice daily in a week. Group C: They treat just with Naproxen. All patients are examined in days 0, 3, 8, 15 and standardized measure of pain will be collected based on the McGill pain questionnaire.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201303106480N5**

Registration date: **2013-04-18, 1392/01/29**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-04-18, 1392/01/29

Registrant information

Name

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Name of organization / entity

Shahrekord University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Deputy for Research Affairs, Shahrekord University of Medical Sciences.

Expected recruitment start date

2013-03-15, 1391/12/25

Expected recruitment end date

2013-06-22, 1392/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of heat and cold therapy on acute back pain in patients referred to Orthopaedic Clinic of Kashani hospital in Shahrekord

Public title

The effectiveness of warm therapy and cold therapy on acute back pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients (men and women) who are between 20 and 50 years old suffering from acute low back pain (LBP); back pain in patients is less than one month) referred to the orthopedic clinic; willingness to participate in the study. Exclusion criteria: history of those diseases, including: cardiovascular, kidney, lung, endocrinology and metabolism diseases and etc; patients who had a history of trauma; patients who consumed other medications to relieve pain other than Naproxen;

patients who were treated with physiotherapy and patients with unwillingness to continue treatment.

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **87**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Shahrekord University of Medical Sciences

Street address

Kashani Blvd, Secretery of Shahrekord University of Medical Sciences, Deputy of Research Affairs

City

Shahrekord

Postal code**Approval date**

2012-01-10, 1390/10/20

Ethics committee reference number

90-10-32

Health conditions studied**1****Description of health condition studied**

Acute back pain

ICD-10 code

M54.5

ICD-10 code description

Low back pain

Primary outcomes**1****Description**

Pain

Timepoint

Before intervention and 15th, 8th, 30th day after intervention

Method of measurement

McGill standard questionnaire

Secondary outcomes

empty

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

Under treatment with oral naproxen 500 mg twice daily and warm water bag daily for 20 minutes twice in a week

Category

Treatment - Other

2**Description**

Under treatment with 500 mg Naproxen twice daily and under treatment with ice for 20 minutes in a day, twice in a week

Category

Treatment - Other

3**Description**

Treated with oral naproxen 500 mg twice a day for one week

Category

Treatment - Drugs

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

Clinic of Ayatallah Kashani Hospital

Full name of responsible person

Dr Morteza Dehghan

Street address

Kashani Blvd

City

Shahrekord

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

Deputy of Research Affairs, Shahrekord University of

Medical Sciences
Full name of responsible person
 Dr Mahmoud Mobasheri
Street address
 Kashani Blvd
City
 Shahrekord
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
 Yes
Title of funding source
 Deputy of Research Affairs, Shahrekord 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
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Person responsible for updating data

Contact

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