

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of topical products extracted from essential oils of Capsicum, Apium graveolen and Mentha plants on the pain intensity in patients with skeletal inflammatory pain

Protocol summary

Study aim

Determine the efficacy of Red pepper extract and Celery and Vinegar, on Skeletal Inflammatory pain

Design

First, 3 groups with the names (red pepper group) and (mint and celery essential oil group) and (mint, celery and red pepper essential oil combination group) were written on paper and placed in a container so that the mentioned number is hidden. Then, each referring patient drew a piece of paper from inside the container and was placed in his / her group. This work continued until reaching the desired sample size(60).

Settings and conduct

Study in Yahya Nejad Hospital, Babol, the orthopedic surgeon's will be conducted with specified conditions, and the entry and exit criteria will be performed, and the placement will be blinded in 3 groups

Participants/Inclusion and exclusion criteria

In this study include criteria were , patients 40 - 70 years , without other bone diseases, pregnancy and breastfeeding, the lack of drug interactions. Exclude criteria were, use of other topical analgesics.

Intervention groups

The first intervention group received Capex ointment (Red pepper), The second group receiving the solution received the CM (Celery and Vinegar), The third group received the intervention received the combination of Red pepper and Celery and Vinegar

Main outcome variables

pain reduction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180827040884N1**

Registration date: **2020-08-20, 1399/05/30**

Registration timing: **retrospective**

Last update: **2020-08-20, 1399/05/30**

Update count: **0**

Registration date

2020-08-20, 1399/05/30

Registrant information

Name

Fatemeh Taghlili

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3239 9079

Email address

fa_taghlili@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2019-02-20, 1397/12/01

Actual recruitment start date

2018-09-23, 1397/07/01

Actual recruitment end date

2019-02-20, 1397/12/01

Trial completion date

2019-08-23, 1398/06/01

Scientific title

Effect of topical products extracted from essential oils of Capsicum, Apium graveolen and Mentha plants on the pain intensity in patients with skeletal inflammatory pain

Public title

Effect of topical products extracted from essential oils of Capsicum, Apium graveolens and Mentha plants on the pain intensity in patients with skeletal inflammatory pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients 40 – 70 years without other bone diseases Dont pregnancy and breastfeeding The lack of drug interactions

Exclusion criteria:

Use of other topical analgesics

Age

From **40 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

First, each patient referred to the clinic was given a special code. All the codes were placed in a container. Then, three envelopes named (A), (B), (C) were selected and given to patients as a blind strain. Then, by drawing lots from the patient code container, a piece of paper was taken out and the desired code was selected from one of the envelopes and the desired intervention group was identified. After the intervention group was identified, the specified code was returned to the code container. So that all participants have an equal chance to choose the intervention group. This work continued until reaching the desired sample size.

Blinding (investigator's opinion)

Single blinded

Blinding description

The drug was delivered to patients with identical tubes that had only a specific code

Placebo

Not used

Assignment

Parallel

Other design features

-

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Islamic Azad University of Babol

Street address

No. 6, Sobhan Apartment, 21 Golestan, Eastern Belt, Babol.

City

Babol

Province

Mazandaran

Postal code

4715763561

Approval date

2018-08-26, 1397/06/04

Ethics committee reference number

IR.IAU.BABOL.REC.1397.006

Health conditions studied

1

Description of health condition studied

Skeletal inflammatory pain

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pain number with Visual Analogue Scale (VAS)

Timepoint

Measurement of pain before intervention and 14 and 30 days after intervention

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

The drug was delivered to patients with identical tubes that had only a specific code, and it was explained to the patient that the drug to be rubbed 1-1.5 inch, three times a day, for a period of four weeks on painful site without massage. First intervention group received a solution by the name of the CM (Mint and Celery) which was prepared Barij Essence Pharmaceutical Company.

Category

Rehabilitation

2

Description

The second intervention group received Capex ointment which was prepared Barij Essence Pharmaceutical Company. It was explained to the patient that the drug to be rubbed 1-1.5 inch, three times a day, for a period

of four weeks on painful site without massage.

Category

Rehabilitation

3

Description

The third intervention group received, combined solution(Capex ointment and CM) which was prepared Barij Essence Pharmaceutical Company. It was explained to the patient that the drug to be rubbed 1-1.5 inch, three times a day, for a period of four weeks on painful site without massage .

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Yahyanejad hospital

Full name of responsible person

Fatemeh taghlili

Street address

Modarres Ave.,Yahyanejad hospital., Babol

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+98 11 3222 3594

Email

yahyanejad@mubabol.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Reza changizi

Street address

Gorgi Abad., Islamic Azad University of Babol

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4715763561

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info@baboliau.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor

organization/entity?

Yes

Title of funding source

Islamic Azad University

Proportion provided by this source

100

Public or private sector

Private

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

Islamic Azad University

Full name of responsible person

Fatemeh taghlili

Position

Faculty member

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

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Position

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Latest degree

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Person responsible for updating data

Contact

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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

No more information

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

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

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

After the study has been completed and the results of the intervention have been obtained, the impact of the intervention will be published as a paper and will be available to interested parties.

When the data will become available and for how long

Start the access period 6 months after publishing

To whom data/document is available

Health and medical professionals

Under which criteria data/document could be used

Only the information results will be provided to those specializing in the field. Statistical information will be limited to the items mentioned in the article.

From where data/document is obtainable

f_taghlili@yahoo.com

What processes are involved for a request to access data/document

After communicating through the e-mail address and the topic related to the research, and the reason for the request, the results will be presented.

Comments