Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

An investigation into the analgesic effects of Apotel and transcutaneous electrical nerve stimulation on post-operative pain management of patients with knee replacement

Protocol summary

Study aim

An investigation into the analgesic effects of Apotel and transcutaneous electrical nerve stimulation on post-operative pain management of patients with knee replacement

Design

This study is clinical trial and double blind. patients will be divided in 2 groups by simple randomization.Groups are parallel.

Settings and conduct

Patients candidate knee joint replacement in Valiasr hospital in Arak will enter this study. This study is double blind. Researcher who complete questionnaire and analyzer and participant are blind (double blind).

Participants/Inclusion and exclusion criteria

Inclusion criteria:People aged 20 to 80 with normal preoperative mobility Exclusion criteria:Patients with neuropathic pain or sensory impairment in the case of surgery, history of previous knee surgery, sensitivity to medications, body mass index more than 40 , no underlying disease

Intervention groups

Intervention group:In the TENS group, 4 pads are placed on each side of the waist around L1 to T10 for half an hour 1, 6, and 12 hours after surgery. Pad sizes are 40 x 100.To study the frequency of the device is set to 100 Hz. The device is for Body Clock Health Care London.With an output of 0 to 110 mA, which is represented by Tasmanim Arman Behbod Company in Iran. control group:In the Apotel group, one gram in 10 ml of normal saline was given in recovery and continued for 24 hours postoperatively.

Main outcome variables

Pain, mean heart rate, mean blood pressure, oxygen saturation percent, opioid intake in 24 hours

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141209020258N127**
Registration date: **2019-12-26, 1398/10/05**
Registration timing: **registered_while_recruiting**

Last update: **2019-12-26, 1398/10/05**
Update count: **0**

Registration date

2019-12-26, 1398/10/05

Registrant information

Name

Fariba Farokhi

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-07, 1397/07/15

Expected recruitment end date

2020-01-21, 1398/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
An investigation into the analgesic effects of Apotel and transcutaneous electrical nerve stimulation on post-operative pain management of patients with knee replacement

Public title
An investigation into the analgesic effects of Apotel and transcutaneous electrical nerve stimulation on post-operative pain management of patients with knee replacement

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
People aged 20 to 80 with normal preoperative mobility

Exclusion criteria:
Patients with neuropathic pain or sensory impairment in the case of surgery History of previous knee surgery Sensitivity to medications Body mass index more than 40 No underlying disease

Age
From **20 years** old to **80 years** old

Gender
Both

Phase
3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **88**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple individual randomization with randomization with envelopes in two groups A and B. In this method, we selected a number of cards or letters as an intervention group and the same number of cards for the control group, then the cards were merged. One card was taken out and its allocation was registered and the card was returned to the other cards after leaving. Then the cards are merged again and we remove another card. This process continues to reach a random sequence according to sample size.

Blinding (investigator's opinion)
Double blinded

Blinding description
This study is double blind. Researcher who complete questionnaire and analyzer and participant are blind (double blind). Outcome assessor and analyzer don't aware from grouping.The person evaluating the outcome is unaware of the grouping. Groups A and B are available to analyzer and outcome assessor.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics comittee of Arak University of Medical Sciences

Street address
Ethics comittee, Research center, Payambar Azam complex, Basij squre ,Sardasht,Arak

City
Arak

Province
Markazi

Postal code
3848176941

Approval date
2018-09-23, 1397/07/01

Ethics committee reference number
IR.ARAKMU.REC.1397.150

Health conditions studied

1

Description of health condition studied
Knee joint replacement

ICD-10 code
M23.9

ICD-10 code description
Internal derangement of knee, unspecified

Primary outcomes

1

Description
Pain

Timepoint
At recovery time, 2, 4, 8, 12 and 24 hours after surgery

Method of measurement
Visual analogue pain questionnaire

2

Description
Amount of narcotic drug used

Timepoint
During 24 hours after surgery

Method of measurement
milligram

3

Description
Mean arterial blood pressure

Timepoint
First and in recovery

Method of measurement
Barometer

4

Description
Mean heart rate
Timepoint
First and in recovery
Method of measurement
Count

5

Description
Oxygen saturation percentage
Timepoint
First and in recovery
Method of measurement
Pulse Oximeter

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the TENS group, 4 pads are placed on each side of the waist around L1 to T10 for half an hour 1, 6, and 12 hours after surgery. Pad sizes are 40 x 100.To study the frequency of the device is set to 100 Hz. The device is for Body Clock Health Care London.With an output of 0 to 110 mA, which is represented by Tasmanim Arman Behbod Company in Iran.
Category
Treatment - Devices

2

Description
Control group: In the Apotel group, one gram in 10 ml of normal saline was given in recovery and continued for 24 hours postoperatively.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Valiasr hospital
Full name of responsible person
Dr Alireza Kamali
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Valiasr Hospital, Valiasr squre, Shahid Shirodi street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Research Center, Payambar Azam Complex, Basij square, Sardasht, Arak
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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
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
Arak University of Medical Sciences
Full name of responsible person
Dr Alireza Kamali
Position
Associate professor
Latest degree
Specialist

Other areas of specialty/work
Anesthesiology
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
When we publish article in journal
When the data will become available and for how long
After the article is published
To whom data/document is available
Researcher in university
Under which criteria data/document could be used
If there are additional questions
From where data/document is obtainable
Dr Alireza Kamali
What processes are involved for a request to access data/document
They have to write letters to the professors and the university
Comments