Comparison the effects of acupuncture, physical modality and home based exercise training on symptoms of knee osteoarthritis

Protocol summary

Summary
Aim: to compare the effects of acupuncture, physical modality and home based exercise training on symptoms of knee osteoarthritis. Patients: all patients with knee osteoarthritis, according to American college of rheumatology (ACR) criteria, referred to the clinic of physical therapy in Firoozgar hospital, Tehran, Iran. Main inclusion criteria were knee pain lasting for 6 months or longer and age between 40-65 years. Main exclusion criteria were receiving NSAIDs during study and exacerbation of symptoms. Sixty patients with knee osteoarthritis were randomly divided into three groups (A,B and C). The acupuncture group (A) received only acupuncture at selected acupoint for knee pain; the physical modality group (B) received TENS (transcutaneous Electrical Nerve Stimulation), ultrasound and hot pack at pain areas. The exercise group (C) received isometric exercise of the knee. Each group received treatment 3 sessions per week for 4 weeks. Evaluating measurement tools were Visual Analogue Scale (VAS) for pain intensity and KOOS questionnaire for function.

General information

Acronym
IRCT registration information
IRCT registration number: IRCT138811163284N1
Registration date:
Registration timing: na

Last update:
Update count: 0
Registration date empty

Registrant information
Name
Dr Bijan Forogh
Name of organization / entity
Iran University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone

Expected recruitment start date
2009-04-21, 1388/02/01
Expected recruitment end date
2009-11-30, 1388/09/09
Actual recruitment start date empty
Actual recruitment end date empty
Trial completion date empty

Scientific title
Comparison the effects of acupuncture, physical modality and home based exercise training on symptoms of knee osteoarthritis

Public title
Effects of acupuncture, physiotherapy and exercise training on knee arthrosis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: 1-Male and female with knee pain lasting for 6 months or longer 2-Age between 40-65 years 3-Normal neurological examination 4-At least one osteophyte at tibiofemoral joint (Kellgren- Lawrence grade >2) 5-Not receiving intra articular injection from 3 months ago 6- Not consuming NSAIDs during last week before study 7-No history of knee surgery 8-No history of treatment with acupuncture 9-No history of cancer, pregnancy and secondary osteoarthritis. Exclusion criteria: 1-Low adherence to treatment 2-Receiving NSAIDs during study 3-Exacerbation of symptoms.

Age
From 40 years old to 65 years old
Gender
Both
Phase
N/A
Groups that have been masked
None
Sample size
Target sample size: 60
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
Vice Chancellor for Research, Iran university of medical sciences
Street address
Hemmat highway
City
Tehran
Postal code
Approval date
empty
Ethics committee reference number
8512

Health conditions studied
1
Description of health condition studied
Knee Osteoarthritis
ICD-10 code
M17.1
ICD-10 code description
Other primary gonarthrosis

Primary outcomes
1
Description
pain, symptoms, and activities of daily living
Timepoint
Before and after treatment
Method of measurement
Koos questionnaire

Secondary outcomes
empty

Intervention groups
1
Description
The acupuncture group (A): acupuncture at selected acupoint for knee pain, 3 sessions per week for 4 weeks
Category
Rehabilitation

2
Description
The physical modality group (B): TENS (transcutaneous electrical nerve stimulation), ultrasond and hot pack at pain areas, 3 sessions per week for 4 weeks.
Category
Rehabilitation

3
Description
The exercise group (C): isometric exercise of the knee, 3 sessions per week for 4 weeks
Category
Rehabilitation

Recruitment centers
1
Recruitment center
Name of recruitment center
Firoozgar hospital
Full name of responsible person
Dr Bijan Forogh, MD
Street address
Behafarin street
City
Tehran

Sponsors / Funding sources
1
Sponsor
Name of organization / entity
Vice Chancellor for Research, Iran university of medical sciences
<table>
<thead>
<tr>
<th><strong>Full name of responsible person</strong></th>
<th>Dr Said Abbas Motavalian</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Street address</strong></td>
<td>Hemmat highway</td>
</tr>
<tr>
<td><strong>City</strong></td>
<td>Tehran</td>
</tr>
<tr>
<td><strong>Grant name</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Grant code / Reference number</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Is the source of funding the same sponsor organization/entity?</strong></td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Title of funding source</strong></td>
<td>Vice Chancellor for Research, Iran university of medical sciences</td>
</tr>
<tr>
<td><strong>Proportion provided by this source</strong></td>
<td>100</td>
</tr>
<tr>
<td><strong>Public or private sector</strong></td>
<td>empty</td>
</tr>
<tr>
<td><strong>Domestic or foreign origin</strong></td>
<td>empty</td>
</tr>
<tr>
<td><strong>Category of foreign source of funding</strong></td>
<td>empty</td>
</tr>
<tr>
<td><strong>Country of origin</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Type of organization providing the funding</strong></td>
<td>empty</td>
</tr>
</tbody>
</table>

### Person responsible for general inquiries

| **Contact** |  |
| **Name of organization / entity** | Iran university of medical sciences |
| **Full name of responsible person** | Dr Mohammad Saleki, MD |
| **Position** | Sport medicin resident |
| **Other areas of specialty/work** |  |
| **Street address** | Firoozgar Hospital |
| **City** | Tehran |
| **Postal code** |  |
| **Phone** | +98 21 8214 1229 |
| **Fax** | +98 21 8894 2970 |
| **Email** | drsaleki@yahoo.com , tannaz.ahadi@yahoo.com |
| **Web page address** |  |

### Person responsible for scientific inquiries

| **Contact** |  |
| **Name of organization / entity** | Iran university of medical sciences |
| **Full name of responsible person** | Dr Tannaz Ahadi, MD |
| **Position** | Assistant Professor / Physiatrist |
| **Other areas of specialty/work** |  |
| **Street address** | Firoozgar Hospital, Behafarin street |
| **City** | Tehran |
| **Postal code** |  |
| **Phone** | +98 21 8214 1229 |
| **Fax** | +98 21 8894 2970 |
| **Email** | drsaleki@yahoo.com , tannaz.ahadi@yahoo.com |
| **Web page address** |  |

### 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 |