Comparison effect of oral & intramuscular injection of methocarbamol and placebo on muscle strain

Protocol summary

Summary
The aim of this study was to explore the effect of oral & intramuscular injection of methocarbamol in comparison to placebo on muscle strain. This study was a clinical trial that was performed between June 2008 to March 2010. The 120 patients with diagnosis of muscle strain with duration of less than 2 weeks were classified by random allocation (3 blocks) into 3 groups with equal numbers. The demographic information and pain intensity (measured by visual analogue scale) were evaluated before start of treatment. The first group (33 cases) received oral methocarbamol (2 tab (1000mg), q4h, for 3 days, then 3 tab, q8h, for 4 days) and naproxen (1 tab (500mg), q12 h for 7 days). The second group (38 cases) received 1 ampule (1000mg) methocarbamol on buttocks and naproxen (1 tab (500mg), q12 h for 7 days). The third group (35 cases) received placebo (1 tab, q12h) and naproxen (1 tab (500mg), q12 h) for 7 days. The pain intensity and rate of recovery was evaluated after end of treatment. Data were analyzed using SPSS software.

General information

Acronym
IRCT registration information
IRCT registration number: IRCT138904014238N1
Registration date: 2010-10-11, 1389/07/19
Registration timing: retrospective

Recruitment status
Recruitment complete

Funding source
Yasuj University of Medical Science

Expected recruitment start date
2008-01-03, 1386/10/13

Expected recruitment end date
2009-12-31, 1388/10/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison effect of oral & intramuscular injection of methocarbamol and placebo on muscle strain

Public title
Effect of oral & intramuscular injection of methocarbamol and placebo on muscle strain

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion: Onset of pain (acute pain,<2week), No history of trauma Exclusion: Radiculopathy, Fracture, Infection, Ligament sprain, Malignancy, Diabetes Mellitus, Thyroid disease, Underlying disease, Rheumatic disease, Myopathy, Motor Neuron disease, Neuropathy

Age
From 20 years old to 65 years old

Gender
Both

Phase
N/A

Groups that have been masked
None

Sample size
Target sample size: 105

Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary IDs
empty

Ethics committees

1
Ethics committee
Name of ethics committee
Yasuj University of Medical Sciences
Street address
Montazeri street
City
Yasuj
Postal code
75919-94799
Approval date
2007-11-20, 1386/08/29
Ethics committee reference number
9/29/8/86

Health conditions studied

1
Description of health condition studied
Muscle strain
ICD-10 code
M60-M79
ICD-10 code description
M62.6

Primary outcomes

1
Description
Pain
Timepoint
In start of treatment and 7-10 days later
Method of measurement
Visual analogue scale

Secondary outcomes
empty

Intervention groups

1
Description
Conventional treatment (Napoxen, 500 mg, q12h, for 7 days) + Placebo (1 tablet, q12h, for 7 days)
Category
Placebo

2
Description
Methocarbamol, Intramuscular, 1 Ampule, 1000 milligram intramuscular in two buttocks + Conventional treatment Naproxen (1 tablet, 500mg, q12h, for 7 days)
Category
Treatment - Drugs

3
Description
Oral Methocarbamol 2 tablet (1000 Milligram, q4h) for 3 days, then 2 tablet (q8h) for 4th days + Conventional treatment Naproxen (1 tablet, 500mg, q12h, for 7 days)
Category
Treatment - Drugs

Recruitment centers

1
Recruitment center
Name of recruitment center
S. Mofateh clinic
Full name of responsible person
Dr Parviz Yazdanpanah
Street address
S. Montazeri street, S. Mofateh clinic
City
Yasuj

Sponsors / Funding sources

1
Sponsor
Name of organization / entity
Yasuj University of Medical Sciences
Full name of responsible person
Dr Parviz Yazdanpanah
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City
Yasuj
Grant name
10506
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Yasuj University of Medical Sciences
Proportion provided by this source
Person responsible for general inquiries

Contact
Name of organization / entity
Yasuj medical College
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Ruhallah Hossini
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Person responsible for scientific inquiries

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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