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), q12h for 7 days). The second group (38 cases) received 1 ampule (1000mg) methocarbamol on buttocks and naproxen (1 tab (500mg), q12h for 7 days). The third group (35 cases) received placebo (1 tab, q12h) and naproxen (1 tab (500mg), q12h) 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

Last update:
Update count: 0
Registration date
2010-10-11, 1389/07/19

Registrant information
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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

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
- **Street address**: S. Montazeri street, S. Mofateh clinic
- **City**: Yasuj

**Grant name**: بودجه معاونت پژوهشی 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

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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