Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Combined nonsteroidal anti-inflammatory drug, muscle relaxant, and caffeine versus nonsteroidal anti-inflammatory drug or mucle relaxant monotherapy for acute mechanical low back and/or cervical pain. A double blind, randomized, multicenter, phase III study.

Protocol summary

Summary

Objective In adults with acute mechanical low back and/or cervical pain the study will compare the efficacy of triple combination (non steroidal anti-inflammatory drug + muscle relaxant + caffeine) in visual analogue scale (VAS) values, as compared to monotherapy (non steroidal anti-inflammatory drug or muscle relaxant). The hypothesis will consider the superiority of the combination therapy Inclusion criteria -Male or female subjects, 18 to 65 years of age -Written informed consent -Having acute mechanical lower back and/or cervical pain -VAS score minimum of 50 mm at time of entry into study. Exclusion criteria -Subject is pregnant or lactating woman , or a woman of childbearing potential not using an acceptable method of contraception -Medical history or physical examination results that suggest the pain, symptoms or signs are caused by a serious medical condition (e.g., fever in the last days, diabetes, cancer, rheumatic diseases, cardiac, liver, renal diseases) -History of active peptic ulcer or gastrointestinal (GI) bleeding, history of gastric pain with NSAIDs, -Known allergies, hypersensitivity, or intolerance to any drugs used in the study -Known or suspected history of alcohol or drug abuse -History of epilepsy or recurrent seizures -Creatinine > 1.3 mg/dl Sample size: 714 Duration: 10 days Primary outcome: pain VAS (visual analogue scale)

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138807012498N1**
Registration date: **2009-10-24, 1388/08/02**
Registration timing: **prospective**
Last update:
Update count: **0**

Registration date

2009-10-24, 1388/08/02

Registrant information

Name

Fabio Ikedo

Name of organization / entity

Aché

Country

Brazil

Phone

0055118372608

Email address

fabio.ikedo@ache.com.br

Recruitment status

Recruitment complete

Funding source

Ache Laboratories

Expected recruitment start date

2009-12-07, 1388/09/16

Expected recruitment end date

2010-06-07, 1389/03/17

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Combined nonsteroidal anti-inflammatory drug, muscle relaxant, and caffeine versus nonsteroidal anti-inflammatory drug or mucle relaxant monotherapy for acute mechanical low back and/or cervical pain. A double blind, randomized, multicenter, phase III study.

Public title
Comparison of a triple therapy versus monotherapy in patients with acute mechanical low back and/or cervical pain
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria -Male or female subjects, 18 to 65 years of age -Written informed consent -Having acute mechanical lower back and/or cervical pain -VAS score minimum of 50 mm at time of entry into study. Exclusion criteria -Subject is pregnant or lactating woman , or a woman of childbearing potential not using an acceptable method of contraception -Medical history or physical examination results that suggest the pain, symptoms or signs are caused by a serious medical condition (e.g., fever in the last days, diabetes, cancer, rheumatic diseases, cardiac, liver, renal diseases) -History of active peptic ulcer or gastrointestinal (GI) bleeding, history of gastric pain with NSAIDs, -Known allergies, hypersensitivity, or intolerance to any drugs used in the study -Known or suspected history of alcohol or drug abuse -History of epilepsy or recurrent seizures -Creatinine > 1.3 mg/dl
Age
From **18 years** old to **65 years** old
Gender
Male

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **714**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Comitê de Ética em Pesquisa da Associação de Assistência à Criança Deficiente
Street address
Av. Prof. Ascendino Reis, 724 – CEP: 04027-000
City
São Paulo
Postal code
Approval date
2009-04-02, 1388/01/13
Ethics committee reference number
008/2009

Health conditions studied

1

Description of health condition studied
Acute mechanical low back and/or cervical pain
ICD-10 code
M54, M54.2
ICD-10 code description
Dorsalgia, Cervicalgia, low back pain

Primary outcomes

1

Description
visual analogue scale (VAS)- pain
Timepoint
3rd day of tretament
Method of measurement
Pain VAS scale

Secondary outcomes

1

Description
quality of life evaluation
Timepoint
first visit and last visit (10 days)
Method of measurement
SF-36 (Medical Otcomes Study 36 – Item Short-Form Health Survey)

Intervention groups

1

Description
naproxen 500 mg + cyclobenzaprine 5 mg + caffeine 100 mg (oral pills, once daily, in the morning); naproxen 500 mg + cyclobenzaprine 5 mg (pills, once daily, in the evening), Duration: 10 days
Category
empty

2

Description
naproxen 500 mg (oral pills, twice a day). Duration: 10 days
Category
empty

3

Description
cyclobenzaprine 5 mg (oral pills, twice a day). Duration: 10 days
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Centro de Pesquisa Clínica do Hospital Abreu Sodré – AACD
Full name of responsible person
Street address
City

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ache Laboratories
Full name of responsible person
Fabio Ikedo
Street address
Rodovia Dutra km 222,2; CEP (ZIP) 07034-904
City
Guarulhos
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ache Laboratories
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Ache Laboratories
Full name of responsible person
Fabio Ikedo
Position
MD; senior clinical research manager
Other areas of specialty/work
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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