

# 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 muscle 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 muscle 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 treatment

**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 Outcomes 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

#### Street address

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fabio.ikedo@ache.com.br

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### Person responsible for scientific inquiries

#### Contact

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### Person responsible for updating data

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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*