

Evaluation of efficacy and safety of aceclofenac injection in the treatment of acute lumbago: a randomised comparative open-labeled multi-centric trial

Submission date 19/09/2006	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 03/10/2006	Overall study status Completed	☐ Protocol
Last Edited 04/10/2006	Condition category Musculoskeletal Diseases	☐ Statistical analysis plan
		☐ Results
		☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

ACELO-0605

Study information

Scientific Title

Study objectives

To evaluate the efficacy and tolerability of aceclofenac injection as compared to diclofenac injection in subjects suffering from acute lumago.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Institutional Ethic Committee approval taken for the study.

Study design

Two arm, open-labeled, multi-centric, randomised, comparative trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Acute Lumbago

Interventions

Group one - intervention treatment: Aceclofenac injection 150 mg twice daily (b.i.d) for two days.

Group two - intervention treatment: Diclofenac injection 75 mg b.i.d for two days.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Aceclofenac

Primary outcome(s)

1. Assessment of overall response to study drugs.
2. Assessment of overall response of subjects to the drug.

Key secondary outcome(s)

1. Assessment of changes in VAS pain at 30 minutes, one, two, four, eight, 24 and 48 hours after the treatment compared with the baseline.
2. Assessment to degree of improvement after eight hours, 24 hours and 48 hours of treatment compared to baseline in:
 - a. pain on movement using a four point scale

- b. functional impairment using a four point scale
- c. pain on pressure in the lumbosacral region using a four point scale
- d. muscle contraction in the lumbosacral region using a four point scale

Completion date

10/08/2006

Eligibility

Key inclusion criteria

1. Patients of either sex, aged over 18 years suffering from acute lumbago (that began less than 48 hours before study entry)
2. Pain intensity more than 50 mm on a 100 mm Visual Analogue Scale (VAS)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

Patients with history of:

1. Recurrent peptic ulcer or duodenal ulcer
2. Gastrointestinal bleeding or other bleeding disorders
3. Significant renal or hepatic impairment
4. Any significant abnormality on preclinical trial screening
5. Pregnant and lactating mothers
6. Patients requiring aspirin at any dose, corticosteroids, anticoagulants, ticlopidine hydrochloride or other drugs affecting platelet function and coagulation, and patients taking hormonal contraceptives or patients allergic to Non Steroidal Anti-Inflammatory Drugs (NSAIDs)

Date of first enrolment

02/05/2006

Date of final enrolment

10/08/2006

Locations

Countries of recruitment

India

Study participating centre

A-4, MIG

Madhya Pradesh

India

452001

Sponsor information

Organisation

Venus Remedies Limited (India)

ROR

<https://ror.org/0169rv113>

Funder(s)

Funder type

Industry

Funder Name

Venus Remedies Limited (India)

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not provided at time of registration