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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

Registration date
03/10/2006

Overall study status
Completed

Last Edited
04/10/2006

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] 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

Contact name
Dr V P Pandey

Contact details
A-4, MIG
A.B.Road
Indore
Madhya Pradesh
India
452001
+91 0731 2532164
vppandey@sancharnet.in

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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

Secondary outcome measures
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

Overall study start date
02/05/2006

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
300

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)

Sponsor details
Intellectual Scientific Division
Research and Development Centre
51-52 Industrial Area
Phase-1
Panchkula
Haryana
India
134113
+91 17 22561244
operations@venusremedies.com

Sponsor type
Industry

Website
http://www.venusremedies.com

ROR
https://ror.org/0169rv113

Funder(s)

Funder type
Industry

Funder Name
Venus Remedies Limited (India)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration