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Aceclofenac and diacerein combination treatment for arthritis

Submission date
07/08/2018

Recruitment status
No longer recruiting

Registration date
22/08/2018

Overall study status
Completed

Last Edited
03/04/2020

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Osteoarthritis is a common progressive disease affecting weight-bearing joints. Though traditionally deemed a degenerative disease, it is now believed that inflammatory pathways also play an important relationship in this disease. Aceclofenac and diacerein are both anti-inflammatory drugs used to treat osteoarthritis; however, they are only used individually, rather than in combination. This study aims to look at the effects of combining Aceclofenac and diacerein.

Who can participate?
Adults with inflammatory osteoarthritis of the knee

What does the study involve?
Patients will be randomised into the study and control groups. Patients in the intervention group will receive treatment with Aceclofenac and diacerein for a year, whereas patients in the control group will receive physiotherapy treatment. For both groups, patients will be assessed for pain, stiffness, physical function and general health, along with completing X-rays and liver and kidney function tests.

What are the possible benefits and risks of participating?
The possible benefit of participating is that the combination of Aceclofenac and diacerein may be more effective than using either drug alone. There are no known risks to participants, and they will be monitored for any side effects through routine physical and laboratory examinations every 3 months.

Where is the study run from?
National Center for Rheumatic Diseases, Kathmandu, Nepal

When is the study starting and how long is it expected to run for?
June 2017 to October 2018

Who is funding the study?
National Center for Rheumatic Disease (Nepal)

Who is the main contact?
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
200/2017 Nepal Health Research Council (NHRC)

Study information

Scientific Title
Efficacy and tolerance of aceclofenac and diacerein combination for inflammatory osteoarthritis

Study objectives
Aceclofenac and diacerein combination used in inflammatory osteoarthritis is more efficacious and safe compared to aceclofenac monotherapy

Ethics approval required
Old ethics approval format

Ethics approval(s)
Nepal Health Research Council (NHRC), 14/03/2018, 200/2017

Study design
Observational prospective open-label randomised case-control study

Primary study design
Observational

Secondary study design
Case-control study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Inflammatory osteoarthritis

Interventions
Patient will be allocated into 2 groups - the intervention group and the control group.
Patients in the intervention group will be treated with Aceclofenac and diacerein. Aceclofenac will be given at the starting dose of 100 mg twice daily for the first 10 days. The dose will then be tapered to 100 mg every day for next 10 days. The dose will then be further reduced to 50 mg per day for next 10 days and a final dose of 50 mg on alternate days will be given for 10 more days. Diacerein will be given at the dose of 50 mg twice daily for the initial 3 months after which the dose will be reduced to 50 mg per day for the next 9 months,
Patients in the control group will be managed with physiotherapy alone.
At the onset of treatment, the Visual Analogue Score (VAS), Health Assessment Questionnaire (HAQ) score, Western Ontario & McMaster Universities Osteoarthritis Index (WOMAC) score and X-ray findings of each patient will be recorded. Follow up will be done regularly at 3 month intervals, where clinical improvement will be recorded with VAS Score, HAQ score, and WOMAC

score. X-rays will be repeated at the end of 1 year. The side effects will also be monitored by careful questioning and physical examination, along with renal and liver function tests and care.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Aceclofenac Diacerein

Primary outcome measure
1. Improvement in pain, assessed using the Visual Analog Scale at 3, 6, 9 and 12 months after beginning treatment, along with every 3 months throughout the 1 year follow-up period
2. Gastrointestinal toxicity of a tapering dose of Aceclofenac and diacerein, assessed at at 3, 6, 9 and 12 months after beginning treatment using:
2.1. Patient history of nausea, vomiting, anorexia, dyspepsia, abdominal pain
2.2. Liver function tests, including tests for bilirubin, aspartate transaminase (SGOT), alanine transaminase (SGPT) and alkaline phosphatase (ALP)
3. Renal toxicity of a tapering dose of Aceclofenac and diacerein, assessed at at 3, 6, 9 and 12 months after beginning treatment using:
3.1. Renal function tests, including tests for urea and creatinine
3.2. Urine r/m/e test (complete urine examination)

Secondary outcome measures
1. Long-term effects of diacerein alone over 1 year, assessed by:
1.1. Visual Analogue Score (VAS) for pain, at 3, 6, 9 and 12 months after beginning treatment, along with every 3 months throughout the 1 year follow-up period
1.2. Western Ontario & McMaster Universities Osteoarthritis Index (WOMAC) score at 3, 6, 9 and 12 months after beginning treatment, along with every 3 months throughout the 1 year follow-up period
1.3. Kellgren-Lawrence Classification of Osteoarthritis (KL grading), determined from an X-ray taken 12 months after beginning treatment and at the end of the 1 year follow-up period
2. Change and maintenance of functional status of patients, assessed using the Western Ontario & McMaster Universities Osteoarthritis (WOMAC) score at 3, 6, 9 and 12 months after beginning treatment
3. Change in physical disability, assessed using the Health Assessment Questionnaire (HAQ) at 3, 6, 9 and 12 months after beginning treatment
4. Change in radiographic findings over 1 year, assessed using the Kellgren-Lawrence Classification of Osteoarthritis (KL grading), determined from an X-ray taken 12 months after beginning treatment

Overall study start date
01/06/2017

Completion date
15/09/2020

Eligibility

Key inclusion criteria
1. Aged 18 years or older
2. Knee pain that worsens on activity and is relieved with rest
3. Early morning pain
4. Reduced medial joint space on AP view X-ray of the knee
5. Knee effusion

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
384

Key exclusion criteria
1. Psychiatric patient
2. Pregnant
3. Breastfeeding
4. No informed consent

Date of first enrolment
01/09/2019

Date of final enrolment
15/04/2020

Locations

Countries of recruitment
Nepal

Study participating centre
National Center for Rheumatic Diseases
Ratopul
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Sponsor information

Organisation
National Center for Rheumatic Diseases

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Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Not defined

Funder Name
National Center for Rheumatic Disease, Kathmandu, Nepal

Results and Publications

Publication and dissemination plan
We intend to publish clinicodemographic data, safety-efficacy results, and future ad-hoc results.

Intention to publish date
30/12/2020

Individual participant data (IPD) sharing plan
The datasets generated during and analysed during the current study will be available upon request from Dr Binit Vaidya (drbvaidya@gmail.com).

IPD sharing plan summary
Available on request