ISRCTN53366886 https://doi.org/10.1186/ISRCTN53366886

A double blinded, placebo-controlled, two-way parallel clinical trial to confirm the safety and efficacy of Pennsaid in the treatment of the osteoarthritic knee

Submission date
25/07/2005

Registration date
26/07/2005

Last Edited
11/04/2008

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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
RA-CP-109

Study information

Scientific Title

Study objectives
To evaluate the efficacy and safety of a topical diclofenac solution compared with a vehicle control solution in the treatment of the symptoms of osteoarthritis of the knee.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Osteoarthritis of the knee

Interventions
Topical diclofenac solution versus vehicle control solution.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Diclofenac

Primary outcome(s)
Change from baseline to final assessment in pain and physical function, assessed using the Western Ontario McMaster Universities Osteoarthritis (WOMAC) subscales, and patient global assessment

Key secondary outcome(s))
Change from baseline to final assessment in stiffness, assessed using the WOMAC subscale

Completion date
31/08/2000

Eligibility

Key inclusion criteria
1. Primary osteoarthritis of the knee characterised by deterioration and abrasion of articular cartilage and/or formation of new bone at the joint surface

2. Age between 40 and 85 years
3. Moderate flare of pain after discontinuation of prior non-steroidal anti-inflammatory drug (NSAID)/analgesic
4. Non-pregnant

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Sensitivity to NSAIDs
2. Severe, uncontrolled systemic disease
3. Gastro-duodenal ulcer
4. Secondary osteoarthritis
5. Corticosteroid use
6. Prior intra-articular viscosupplementation
7. Fibromyalgia

Date of first enrolment
01/11/1999

Date of final enrolment
31/08/2000

Locations

Countries of recruitment
Canada

Study participating centre
Malvern Medical Centre
Toronto, Ontario
Canada
M1B 4Y9

Sponsor information

Organisation
Dimethaid Research Inc. (Canada)

ROR
https://ror.org/00qe6gb33

Funder(s)

Funder type
Industry

Funder Name
Dimethaid Research Inc. (Canada)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results	08/08/2005		Yes	No