

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	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 26/07/2005	Overall study status Completed	<input type="checkbox"/> Protocol <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 11/04/2008	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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