

# 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

<b>Submission date</b> 25/07/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 26/07/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 11/04/2008	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Dr Philip Baer

### 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?
<a href="#">Results article</a>	Results	08/08/2005		Yes	No