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Topical or Oral Ibuprofen

Submission date	Recruitment status	[_] Prospectively registered
25/04/2003	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
25/04/2003	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
24/08/2009	Musculoskeletal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 01/09/02

Study information

Scientific Title
Are topical or oral ibuprofen equally effective for the treatment of chronic knee pain in older people?

Acronym
TOIB

Study objectives
1. To ascertain, for older people with knee pain, if oral and topical ibuprofen are equally effective at reducing pain and disability in a randomised controlled trial
2. To compare the incidence of adverse effects from oral and topical ibuprofen used to treat older people with knee pain
3. To compare the cost effectiveness of oral and topical ibuprofen used for treatment of older people with knee pain
4. To compare expected and actual satisfaction with treatment, with effectiveness of oral and topical ibuprofen for older people with knee pain
5. To explore how older people's expressed preferences for, and previous use of, oral or topical medication for chronic knee pain influences treatment effectiveness
6. To explore older people's beliefs about and expectations of treatments for chronic knee pain

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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Knee pain

Interventions

The two interventions being compared are the GP's recommendation (either a prescription or advice to get an over-the-counter preparation) to use either topical or oral ibuprofen. For those whose chosen/allocated treatment is oral ibuprofen, practices are asked to use no more than 1.2 g per day. Treatments for knee pain other than NSAIDs may be used as each patient's doctor thinks appropriate.

Participants are sent postal questionnaires three, six, 12 and 24 months after randomisation. One year and two years after randomisation participants are asked to visit the practice to have their blood pressure and respiratory function measured and blood taken for full blood count, serum ferritin, creatinine and liver function tests. The medical records are examined one year after randomisation to identify unplanned hospital admissions, and after two years (or at the end of the study) to collect health service activity data and confirm reported changes in medication and adverse effects.

Intervention Type
Drug

Phase
Not Specified

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

Primary outcome measure
The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) questionnaire, which measures pain and disability in the preceding 48 hours.

Secondary outcome measures
1. The postal version of the Chronic Pain Grade, which measures pain and disability over the preceding six months
2. The Euro Quality of Life questionnaire (EQ-5D), a measure of health-related quality of life
3. The 36-item Short Form health survey (SF-36) version 2, a different measure of health related quality of life
4. A question assessing satisfaction with treatment

Overall study start date
01/07/2002

Completion date
31/08/2006

Eligibility

Key inclusion criteria
1. Aged 50 or over
2. Have ever had pain in or around the knee on most days for at least a month and have experienced knee pain for more than three months out of the preceding year
3. General Practitioner (GP) consultation, or treatment, for knee pain in the preceding three years
4. Informed consent

5. Agreement to use chosen or allocated treatment
6. GP agreement to prescribe oral/topical ibuprofen
7. Ability to complete postal questionnaires

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
283

Key exclusion criteria
1. Peptic ulceration (past or current)
2. Current moderate or severe indigestion
3. Previous severe adverse reaction to Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)
4. Hypertension (systolic Blood Pressure [BP] of 155 mmHg or more or a diastolic BP of 105 mmHg or more)
5. Uncontrolled heart failure
6. Creatinine greater than 140 mmol/L
7. Abnormal liver function sufficient to contraindicate use of NSAIDs (as liver function tests performed and reference ranges vary between different laboratories, this decision is at the discretion of the participant's GP)
8. GP request not to include
9. Serious psychological or psychiatric disorders (including dementia)
10. Previous knee replacement/s or awaiting knee surgery
11. Inflammatory arthropathy
12. Pain referred from hip or back
13. Serious injury within six months
14. Currently on anticoagulants or oral steroids
15. Anaemia (Haemoglobin [Hb] less than 12.4 g/L for men or less than 11.8 g/L for women)
16. Disseminated malignancy

To meet the American College of Rheumatologists (ACR) clinical criteria for osteoarthritis of the knee, patients need to have knee pain, as defined for this study, and meet three out of the following six criteria:
1. Aged over fifty
2. Less than 30 minutes morning stiffness
3. Crepitus
4. Bony tenderness
5. Bony enlargement
6. No palpable warmth

Date of first enrolment
01/07/2002

Date of final enrolment

31/08/2006

Locations

Countries of recruitment
England

United Kingdom

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Sponsor type
Government

Website
http://www.dh.gov.uk/en/index.htm

ROR
https://ror.org/03sbpja79

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (UK)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	07/11/2005		Yes	No
Results article	main results publication at	19/01/2008		Yes	No
Other publications	HTA monograph at	01/05/2008		Yes	No
Results article	cost-effectiveness results	01/07/2008		Yes	No