

Managing knee pain with simple analgesia: the efficacy, cost and adherence implications

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| Submission date 23/10/2000 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| Registration date 23/10/2000 | Overall study status Completed | <input type="checkbox"/> Protocol |
| Last Edited 30/07/2009 | Condition category Musculoskeletal Diseases | <input type="checkbox"/> Statistical analysis plan |
| | | <input type="checkbox"/> Results |
| | | <input type="checkbox"/> Individual participant data |
| | | <input type="checkbox"/> Record updated in last year |

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
G9900285

Study information

Scientific Title

Study objectives

1. Treatment trial: to test the hypothesis that continuous use of simple analgesia in osteoarthritis (OA) knee is more effective in reducing pain in the affected joint than analgesia used on an 'as required' basis.
2. Adherence trial: to test the hypothesis that a simple intervention delivered by practice nurses can increase adherence to continuous analgesia.

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

Treatment trial:

1. Continuous use paracetamol (4 g daily)
2. 'As required' paracetamol (up to 4 g daily as needed)

Adherence trial (all patients in treatment group 1):

1. Individualised educational intervention to promote adherence delivered by practice nurse
2. No intervention

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Paracetamol

Primary outcome(s)

Treatment trial: pain in the affected joint measured by 100 mm visual analogue scale

Adherence trial: Proportion of patients who adhere to the regimen for continuous paracetamol

Key secondary outcome(s)

Not provided at time of registration

Completion date

01/03/2002

Eligibility

Key inclusion criteria

1. Male and female patients over 55 years
2. Clinical diagnosis osteoarthritis of the knee
3. Current joint pain score greater than 30 on a 10 mm visual analogue scale

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Senior

Sex

All

Key exclusion criteria

1. Serious concomitant illness
2. Other pain-related conditions
3. Abnormal liver function tests
4. History of analgesic abuse or overdose
5. Severe OA awaiting joint replacement
6. Psychological disorders requiring treatment
7. Patients unable to follow instructions/complete questionnaires.
8. Use of over the counter medication containing paracetamol for duration of the study

Date of first enrolment

01/09/1999

Date of final enrolment

01/03/2002

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Academic Rheumatology

Nottingham

United Kingdom

NG5 1PB

Sponsor information

Organisation

Medical Research Council (MRC) (UK)

Funder(s)

Funder type

Research council

Funder Name

Medical Research Council (MRC) (UK)

Alternative Name(s)

Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration