ISRCTN87954265 https://doi.org/10.1186/ISRCTN87954265

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

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

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

**Contact name**
Dr Alison Carr

**Contact details**
Academic Rheumatology
University of Nottingham
Clinical Sciences Building
Nottingham
United Kingdom
NG5 1PB

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
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

## Secondary study design
Randomised controlled trial

## Study setting(s)
Not specified

## Study type(s)
Treatment

## Participant information sheet

## 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 measure
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

### Secondary outcome measures
Not provided at time of registration

### Overall study start date
01/09/1999

### 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

### Age group
Senior

### Sex
Both

### Target number of participants
244 - Discontinued after March 2002

### 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**
England

United Kingdom

**Study participating centre**
**Academic Rheumatology**
Nottingham
United Kingdom
NG5 1PB

# Sponsor information

**Organisation**
Medical Research Council (MRC) (UK)

**Sponsor details**
20 Park Crescent
London
United Kingdom
W1B 1AL
+44 (0)20 7636 5422
clinical.trial@headoffice.mrc.ac.uk

**Sponsor type**
Research council

**Website**
http://www.mrc.ac.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, MRC

**Funding Body Type**
Government organisation

**Funding Body Subtype**
National government

**Location**
United Kingdom

# 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