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

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

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