ISRCTN14558398 https://doi.org/10.1186/ISRCTN14558398

Modification of chronic oral nonsteroidal anti-inflammatory drug (NSAID) requirement; feasibility, patient benefit and cost-effectiveness.

Submission date
23/01/2004

Recruitment status
No longer recruiting

Registration date
23/01/2004

Overall study status
Completed

Last Edited
04/02/2010

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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
95XX2

Study information

Scientific Title

Study objectives
The researchers will test the hypothesis that chronic oral NSAID requirement may be eliminated or reduced in the majority of community based patients by the use of simple, alternative management strategies.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from local medical ethics committee

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Osteoarthritis; regional locomotor pain

Interventions
Patients will be randomised, stratified according to joint or non-joint disorder, to receive either:
1. General advice on NSAIDs (group 1)
2. Reduced NSAIDs plus advice on alternative treatments for their painful locomotor condition (group 2). Group 2 patients will be asked to stop or at least reduce, their NSAID use. For each patient in group 2, appropriate alternative treatment options will be chosen from a defined list.
A six week follow-up assessment will be made of which interventions were utilised.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/10/1995

Completion date
31/03/1997

Eligibility

Key inclusion criteria
Two general practices with computer generated register data will be invited to participate. Up to 260 patients receiving regular prescriptions for NSAIDs for regional locomotor pain will be identified according to the following criteria.
1. Adult (18 years or older, no upper age limit)
2. Oral NSAID prescriptions to cover at least 6 of the previous 12 months
3. Last prescription within 6 weeks of induction into study
4. Osteoarthritis or regional locomotor pain (e.g. shoulder lesion, neck pain, back pain) as the reason for prescription

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
260

Key exclusion criteria
Defined inflammatory arthritis (e.g. rheumatoid arthritis, ankylosin spondylitis, gout), bone malignancy or non-locomotor pain as reason for prescription (obtained from GP records)

Date of first enrolment
01/10/1995

Date of final enrolment

31/03/1997

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Rheumatology Unit
Nottingham
United Kingdom
NG5 1PB

Sponsor information

Organisation
NHS R&D Regional Programme Register - Department of Health (UK)

Sponsor details
The Department of Health
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name

NHS Executive Trent (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?
Results article	results	01/01/2002		Yes	No