ISRCTN78142229 https://doi.org/10.1186/ISRCTN78142229

Active management of rheumatoid arthritis (RA)

Submission date 30/09/2004	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 30/09/2004	**Overall study status** Completed	
Last Edited 14/11/2014	**Condition category** Musculoskeletal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Christina Estrach

Contact details
Specialist Registrar in Rheumatology
Rheumatology Unit
Whiston Hospital
Prescot
United Kingdom
L35 5DR
+44 (0)151 426 8270

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0237084064

Study information

Scientific Title

Study objectives
The aim of this study is to assess whether the use of an integrated care pathway for the management of rheumatoid arthritis improves outcome. The care pathway attempts to optimise the treatment of RA incorporating all the features of current good practice. It sets out precise treatment decisions based on a validated disease activity score rather than decisions been made on an ad hoc basis by the staff reviewing the patient in out patients.

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
Musculoskeletal Diseases: Rheumatoid arthritis (RA)

Interventions
Randomised to either the care pathway or conventional outpatient review before any changes to their DMARD therapy are made. The control group (50 subjects) will be the patients receiving standard rheumatological care.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Larsen radiological score at 1 year and 2 years
2. Health Assessment Questionnaire (HAQ) assessment at baseline and every 6 months

Secondary outcome measures
1. Assessment of remission at 1 and 2 years
2. Number of DMARDs (disease-modifying anti-rheumatic drugs) and dosage at 1 and 2 years
3. Admissions to the ward with active RA during course of the study

Overall study start date
15/08/2000

Completion date
14/08/2003

Eligibility

Key inclusion criteria
Patients attending the Rheumatology service at St Helens & Knowsley NHS Hospitals with active RA, who are on no more than one disease-modifying anti-rheumatic drug (DMARD), will be invited to participate in the study. Inclusion criteria:
1. Patients with active inflammatory polyarthropathy
2. Age 18 or over
3. On no DMARDs or monotherapy
4. Informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
100 subjects - 50 to each arm of the study

Key exclusion criteria
1. Inflammatory disease due to psoriatic arthritis or other clear or suspected cause other than RA
2. Pregnancy at the time of enrolment or planned during the course of the next 3 years
3. On more than one DMARD at time of enrolment
4. Severe systemic disease or major co-morbidity

Date of first enrolment
15/08/2000

Date of final enrolment
14/08/2003

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Specialist Registrar in Rheumatology
Prescot
United Kingdom
L35 5DR

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
St Helens and Knowsley Hospitals NHS Trust (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