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Active management of rheumatoid arthritis (RA)

Submission date
30/09/2004

Recruitment status
No longer recruiting

Registration date
30/09/2004

Overall study status
Completed

Last Edited
14/11/2014

Condition category
Musculoskeletal Diseases

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

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

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

Key secondary outcome(s)
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

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
United Kingdom

England

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

Sponsor information

Organisation
Department of Health

Funder(s)

Funder type
Government

Funder Name
St Helens and Knowsley Hospitals NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration