

Active management of rheumatoid arthritis (RA)

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| Submission date 30/09/2004 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| Registration date 30/09/2004 | Overall study status Completed | <input type="checkbox"/> Protocol |
| Last Edited 14/11/2014 | Condition category Musculoskeletal Diseases | <input type="checkbox"/> Statistical analysis plan |
| | | <input type="checkbox"/> Results |
| | | <input type="checkbox"/> Individual participant data |
| | | <input type="checkbox"/> Record updated in last year |

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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

Study design

Randomised controlled trial

Primary study design

Interventional

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