

# Active management of rheumatoid arthritis (RA)

<b>Submission date</b> 30/09/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 30/09/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 14/11/2014	<b>Condition category</b> 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

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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