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A randomised, controlled study of outcome and cost effectiveness for Rheumatoid Arthritis (RA) patients attending nurse-led rheumatology clinics: a nationwide multi-centre study

Submission date
13/09/2007

Recruitment status
No longer recruiting

Registration date
21/09/2007

Overall study status
Completed

Last Edited
21/12/2011

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
ARC Grant Ref: 17632

Study information

Scientific Title

Study objectives
The outcomes from nurse-led clinics will be non-inferior to those obtained by physician led clinics, but at a lower cost.

Please note that as of 07/06/10 this record has been updated to included changes in the number of participants, and sponsor details (Arthritis Research Campaign [ARC] are now known as Arthritis Research UK). Please also note that the end date of this trial has been extended from 30 /06/2010 30/06/2011

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Leeds (West) Research Ethics Committee on the 4th January 2007 (REC ref: 06/Q1205/198).

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Diagnostic

Participant information sheet

Health condition(s) or problem(s) studied
Rheumatoid arthritis

Interventions
Patients will be randomly assigned to one of two groups:
1. A Clinical Nurse Specialist group (Experimental Group [EG])
2. A Rheumatologist group (Control Group [CG])

Both the CNS and the Rheumatologist will continue their usual management practice, including making referrals to any members of the multidisciplinary team, changing treatments etc. All interventions undertaken and referrals made by the CNS and the Rheumatologist should be noted on the schedule provided. Any changes to medication and the length of the consultation should also be documented on the schedule.

Total duration for each patient (in both Experimental group and Control group is 1 year - 56 weeks)

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The 28-item Disease Activity Scale (DAS-28) score, undertaken by an independent assessor at recruitment visit, and weeks 0, 13, 26, 39 and 52.

Secondary outcome measures
Secondary measures include both clinical, haematological and questionnaire data:
1. C-Reactive Protein (CRP) or Erythrocyte Sedimentation Rate (ESR)
2. Pain intensity measured on a 10 cm Visual Analogue Scale (VAS)
3. Length of morning stiffness in hours and minutes
4. Fatigue measured on a 10 cm VAS

Questionnaires comprise the following:
5. Health Assessment Questionnaire (HAQ), completed at recruitment visit, week 26 and week 52
6. Hospital Anxiety and Depression Scale (HAD), completed at recruitment visit, week 26 and week 52
7. Leeds Satisfaction Questionnaire (LSQ), completed at recruitment visit, week 26 and week 52
8. The Arthritis Self Efficacy Scale (ASES), completed at recruitment visit, week 26 and week 52
9. Rheumatoid Arthritis Quality of Life questionnaire (RAQoL), completed at recruitment visit, week 26 and week 52
10. EuroQoL (EQ-5D) health outcome instrument, completed at recruitment visit, and weeks 0, 13, 26, 39 and 52

Overall study start date
01/09/2007

Completion date
30/06/2011

Eligibility

Key inclusion criteria
1. Positive diagnosis of RA as defined by the American Rheumatism Association
2. Aged 18 years or above
3. Ability to complete questionnaires unaided

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
As of 07/06/10: 164 (at time of registration: 260)

Key exclusion criteria
1. Patients unwilling to be randomised to a Clinical Nurse Specialist (CNS) or Rheumatologist group
2. Patients suffering from unstabilised concomitant disease
3. Patients awaiting surgery
4. Patients who have already received care from the practitioners involved in the study

Date of first enrolment
01/09/2007

Date of final enrolment
30/06/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Academic and Clinical Unit for Musculoskeletal Nursing (ACUMeN)
Leeds
United Kingdom
LS7 4SA

Sponsor information

Organisation
Arthritis Reseach UK (UK)

Sponsor details
Copeman House
St Mary's Court
St Mary's Gate
Chesterfield
United Kingdom
S41 7TD

Sponsor type
Charity

Website
http://www.arthritisresearchuk.org/

ROR
https://ror.org/02jkpm469

Funder(s)

Funder type
Charity

Funder Name
Arthritis Reseach UK (UK) (Grant Ref: 17632)

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	01/06/2009		Yes	No
Results article	results	01/08/2011		Yes	No