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The effect of patient education on compliance with drug therapy for rheumatoid arthritis

Submission date	Recruitment status	[ ] Prospectively registered
30/07/2002	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
30/07/2002	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
09/09/2009	Musculoskeletal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
B0508

Study information

Scientific Title

Study objectives
Treatment of rheumatoid arthritis (RA) by disease-modifying drugs in which dosage is not symptom driven, is subject to substantial variation in compliance. Our previous work, using a novel pharmacological 'gold standard' for the measurement of compliance in which D-penicillamine was labelled with a homeopathic dose of phenobarbitone, showed that 42% of patients failed to follow instructions of dosage. It is proposed to use the same objective technique, validated clinical measures and a proven knowledge questionnaire, to investigate the effect on compliance of two different levels of patient education amongst RA 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)
Not specified

Study type(s)
Other

Participant information sheet

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

Interventions
Experimental group received a patient education programme

Intervention Type
Other

Phase
Not Specified

Primary outcome measure

It is anticipated that effective education will enhance compliance leading to better drug utilisation and improved patient outcome.

Secondary outcome measures
Not provided at time of registration

Overall study start date
12/01/1993

Completion date
31/08/1998

Eligibility

Key inclusion criteria
1. All patients deemed by the consultant rheumatologist to require dPenicillamine (DPA) as their disease modifying anti-rheumatic drug (DMARD)
2. Over 18 years of age
3. Plasma Viscosity (PV) ≤1.75
4. Cysteine rich protein (CRP) ≤10
5. Articular index 15 or less than
6. Morning stiffness ≤45 min
7. Pain level moderate/severe

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
Not provided at time of registration

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
12/01/1993

Date of final enrolment
31/08/1998

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
CPU (Rheumatism Research)
Leeds
United Kingdom
LS7 4SA

Sponsor information

Organisation
Arthritis Research Campaign (ARC) (UK)

Sponsor details
Copeman House
St Mary's Court
St Mary's Gate
Chesterfield
Derbyshire
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Sponsor type
Charity

Website
http://www.arc.org.uk

ROR
https://ror.org/02jkpm469

Funder(s)

Funder type
Charity

Funder Name

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	01/09/2001		Yes	No