

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

<b>Submission date</b> 30/07/2002	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 30/07/2002	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 09/09/2009	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> 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**  
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)  $\leq 1.75$
4. Cysteine rich protein (CRP)  $\leq 10$
5. Articular index 15 or less than
6. Morning stiffness  $\leq 45$  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

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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?
<a href="#">Results article</a>	results	01/09/2001		Yes	No