

# Control of Rheumatoid Arthritis (RA) by oral tolerance

<b>Submission date</b> 18/07/2002	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 18/07/2002	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 04/10/2007	<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

**Contact name**  
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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
S0523

# Study information

## Scientific Title

## Study objectives

Not provided at time of registration

## 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)

Treatment

## Participant information sheet

## Health condition(s) or problem(s) studied

Rheumatoid arthritis

## Interventions

Patients were randomly assigned to receive either 0.05 mg, 0.5 mg or 5 mg daily of bovine type II collagen (CII) or placebo for six months

## Intervention Type

Drug

## Phase

Not Specified

## Drug/device/biological/vaccine name(s)

Bovine type II collagen

## Primary outcome measure

Not provided at time of registration

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

01/01/1998

**Completion date**

01/01/2000

## Eligibility

**Key inclusion criteria**

1. RA patients aged over 18 and fulfilling the 1987 American College of Rheumatology (ACR) criteria for the diagnosis of RA were entered into the study after giving their written informed consent
2. Patients must have had the disease at least two years and have failed at least one Slow Acting Anti-Rheumatic Drug (SAARD)
3. All the patients had to have active arthritis defined by the presence of three out of four clinical criteria: three or more swollen joints, six or more tender joints, early morning stiffness over 45 minutes and Erythrocyte Sedimentation Rate (ESR) over 28 mm/h. Oral steroid treatment was permitted if the dose was more than 10 mg/day

**Participant type(s)**

Patient

**Age group**

Not Specified

**Sex**

Not Specified

**Target number of participants**

Not provided at time of registration

**Key exclusion criteria**

Not provided at time of registration

**Date of first enrolment**

01/01/1998

**Date of final enrolment**

01/01/2000

## Locations

**Countries of recruitment**

England

United Kingdom

**Study participating centre**  
**Academic Department of Rheumatology**  
London  
United Kingdom  
SE22 8PT

## **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**

Arthritis Research Campaign (UK)

## **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