

Control of Rheumatoid Arthritis (RA) by oral tolerance

Submission date 18/07/2002	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 18/07/2002	Overall study status Completed	☐ Protocol
Last Edited 04/10/2007	Condition category Musculoskeletal Diseases	☐ Statistical analysis plan
		☒ Results
		☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Ernest Choy

Contact details
Academic Department of Rheumatology
GKT School of Medicines
King's College Hospital (Dulwich)
East Dulwich Grove
London
United Kingdom
SE22 8PT
+44 (0)20 7346 6446

Additional identifiers

Protocol serial number
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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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

United Kingdom

England

Study participating centre

Academic Department of Rheumatology

London

United Kingdom

SE22 8PT

Sponsor information

Organisation

Arthritis Research Campaign (ARC) (UK)

ROR

<https://ror.org/02jkpm469>

Funder(s)

Funder type

Charity

Funder Name

Arthritis Research Campaign (UK)

Results and Publications

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