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Control of Rheumatoid Arthritis (RA) by oral tolerance

Submission date	Recruitment status	[_] Prospectively registered
18/07/2002	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
18/07/2002	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
04/10/2007	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
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
St Mary's Court
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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?
Results article	Results	01/09/2001		Yes	No