ISRCTN65477168 https://doi.org/10.1186/ISRCTN65477168

A randomised controlled study of combination therapy in rheumatoid arthritis (RA) patients with a suboptimal response to sulphasalazine

Submission date 10/07/2002	**Recruitment status** No longer recruiting
Registration date 10/07/2002	**Overall study status** Completed
Last Edited 02/10/2007	**Condition category** Musculoskeletal Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr H Capell

Contact details
Centre for Rheumatic Diseases
Glasgow Royal Infirmary
Castle Street
Glasgow
United Kingdom
G4 0SF
+44 (0)141 211 4965
hilary.capell@northglasgow.scot.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

C0640

Study information

Scientific Title

Acronym
MASCOT

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
Sulphasalazine will be used as a disease modifying agent for 6 months, target dose 40 mg/kg (to maximum tolerated dose or 4 g daily as maximum permitted dose). At 6 months those with a suboptimal response defined below will be randomly allocated to:
1. Sulphasalazine and methotrexate placebo
2. Sulphasalazine and active methotrexate
3. Active methotrexate and sulphasalazine placebo

The maximum permitted dose of methotrexate will be 30 mg/week or methotrexate placebo. The maximum permitted dose of sulphasalazine will be 4 g/daily and no intra-articular or intramuscular steroid permitted within 1 month of the 6 month and 18 month assessments. All

patients will receive weekly folic acid 5 mg daily between 6 and 18 months whether allocated to group 1, 2 or 3.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Sulphasalazine, methotrexate, folic acid

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
31/07/2002

Completion date
29/04/2005

Eligibility

Key inclusion criteria
1. Male or female
2. Age 18 - 75 years
3. Onset of disease after age 16
4. Disease duration less than 5 years
5. Active inflammatory arthritis which is defined as six or more swollen joints plus two of the following:
5.1. Morning stiffness more than 45 minutes
5.2. Nine or more tender joints
5.3. Erythrocyte Sedimentation Rate (ESR) more than 28 mm/h

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
31/07/2002

Date of final enrolment
29/04/2005

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Centre for Rheumatic Diseases
Glasgow
United Kingdom
G4 0SF

Sponsor information

Organisation
Arthritis Research Campaign (ARC) (UK)

Sponsor details
Copeman House
St Mary's Court
St Mary's Gate
Chesterfield
Derbyshire
United Kingdom
S41 7TD
-
info@arc.org.uk

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	01/02/2007		Yes	No