

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

<b>Submission date</b> 10/07/2002	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 10/07/2002	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 02/10/2007	<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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### Contact details

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## Additional identifiers

### Protocol serial number

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

**Study type(s)**

Treatment

**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(s)**

Not provided at time of registration

**Key secondary outcome(s)**

Not provided at time of registration

**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

**Healthy volunteers allowed**

No

**Age group**

Not Specified

**Sex**

Not Specified

**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**

United Kingdom

Scotland

**Study participating centre**  
**Centre for Rheumatic Diseases**  
Glasgow  
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## 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?
<a href="#">Results article</a>	Results	01/02/2007		Yes	No