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The British rheumatoid outcome study group (BROSG) trial of symptomatic versus aggressive therapy in established rheumatoid arthritis

Submission date 25/04/2003	**Recruitment status** No longer recruiting
Registration date 25/04/2003	**Overall study status** Completed
Last Edited 24/08/2009	**Condition category** Musculoskeletal Diseases

[ ] 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
Prof Deborah Symmons

Contact details
ARC Epidemiology Research Unit
University of Manchester
Oxford Road
Stopford Building
Manchester
United Kingdom
M13 9PT
+44 (0)161 275 5044
deborah@fs1.ser.man.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 94/45/02

Study information

Scientific Title

Acronym
BROSG

Study objectives
This multi-centre observer-blinded controlled trial will compare the outcome, in terms of disability, of two groups of 240 RA patients with 5-20 years disease duration. Group 1 will be managed predominantly in primary care with the goal of controlling joint pain and stiffness. Group 2 will be predominantly in the rheumatology clinic with the goal of controlling symptoms and suppressing clinical laboratory evidence of inflammation. Only Group 2 will be eligible to receive cytotoxic drugs and parenteral steroids. Both groups will attend an annual review clinic to be screened for the complications of RA. Algorithms will guide physicians in their choice of drugs. The study will include assessment of direct and indirect costs. The multi-professional project team will include clinicians, an epidemiologist, statistician, computer scientist and a health economist.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Multi-centre observer-blinded controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Screening

Participant information sheet

Health condition(s) or problem(s) studied
Rheumatoid arthritis

Interventions

Group 1 will be managed predominantly in primary care with the goal of controlling joint pain and stiffness. Group 2 will be predominantly in the rheumatology clinic with the goal of controlling symptoms and suppressing clinical laboratory evidence of inflammation. Only Group 2 will be eligible to receive cytotoxic drugs and parenteral steroids.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/05/1997

Completion date
31/07/2002

Eligibility

Key inclusion criteria
Patients with rheumatoid arthritis of 5-20 years duration

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
480

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/05/1997

Date of final enrolment
31/07/2002

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
ARC Epidemiology Research Unit
Manchester
United Kingdom
M13 9PT

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Quarry House
Quarry Hill
Leeds
United Kingdom
LS2 7UE
+44 (0)1132 545 843
Sheila.Greener@doh.gsi.gov.uk

Sponsor type
Government

Website
http://www.dh.gov.uk/en/index.htm

ROR
https://ror.org/03sbpja79

Funder(s)

Funder type
Government

Funder Name

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	01/09/2005		Yes	No