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

Submission date	Recruitment status No longer recruiting	Prospectively registered		
25/04/2003		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
25/04/2003	Completed	[X] Results		
Last Edited 24/08/2009	Condition category Musculoskeletal Diseases	[] 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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Additional identifiers

Protocol serial number 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

Study type(s)

Screening

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(s)

Not provided at time of registration

Key secondary outcome(s))

Not provided at time of registration

Completion date

31/07/2002

Eligibility

Key inclusion criteria

Patients with rheumatoid arthritis of 5-20 years duration

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

England

Study participating centre ARC Epidemiology Research Unit

Manchester United Kingdom M13 9PT

Sponsor information

Organisation

Department of Health (UK)

ROR

https://ror.org/03sbpja79

Funder(s)

Funder type

Government

Funder Name

NIHR Health Technology Assessment Programme - HTA (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	01/09/2005		Yes	No