

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	<input type="checkbox"/> Prospectively registered
Registration date 25/04/2003	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 24/08/2009	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<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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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

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United Kingdom

LS2 7UE

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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