

Rehabilitation of Patients with Rheumatoid Arthritis (RA): Changes in Muscle, Functional and Biochemical Parameters

Submission date 23/01/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 23/01/2004	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 26/11/2009	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
Dr Michael Hurley

Contact details
Physiotherapy Division
Rehabilitation Research Unit
King's College London
King's Healthcare (Dulwich)
East Dulwich Grove
London
United Kingdom
SE22 8PT
+44 (0)20 73466022
mike.hurley@kcl.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

PCD/A1/87

Study information

Scientific Title

Study objectives

Rheumatoid arthritis is an extremely debilitating condition that attacks and destroys synovial joints. Atrophy of muscles acting across damaged joints is a common clinical feature of RA and contributes to disability. Although physiotherapy is frequently requested to improve strength and function, its efficacy is uncertain. Moreover, recent research has suggested reperfusion-injury following exercise of RA joints may be one of the mechanisms of joint destruction. The objectives of the research were:

1. To compare the differences in lower and upper limb sensorimotor function, functional performance and patient-reported disability between healthy subjects and patients with rheumatoid arthritis (RA).
2. To investigate the effect of a brief, clinically applicable course of exercise rehabilitation on these variables and establish whether rehabilitation exacerbates disease activity. Separate knee and elbow trials were conducted.

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)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Arthritis (rheumatoid)

Interventions

The intervention consisted of 10 exercise sessions (twice a week for 5 weeks) at a hospital out-patient department. Exercises were tailored to address each individual patient's disabilities.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

1. Knee Study: Isometric quadriceps strength
2. Elbow Study: Elbow flexor strength

Secondary outcome measures

1. Knee Study:
 - 1.1. Voluntary quadriceps activation
 - 1.2. Knee joint position sense
 - 1.3. 4 common activities of daily living
 - 1.4. Health Assessment Questionnaire (HAQ)
 - 1.5. Disease Repercussion Profile
 - 1.6. Clinical measures of disease activity in RA
 - 1.7. Serum concentrations of IL-1, IL-6, TNF-alpha
2. Elbow Study:
 - 2.1. Voluntary flexor activation
 - 2.2. Elbow joint position sense
 - 2.3. HAQ
 - 2.4. Arthritis Impact Measurement Scale-2
 - 2.5. Clinical measures of disease activity

Overall study start date

01/04/1996

Completion date

01/07/1999

Eligibility

Key inclusion criteria

Patients with knee and elbow rheumatoid arthritis.

1. Knee study: 133 participants were recruited to the cross-sectional study, 108 RA patients and 25 healthy participants. 93 patients were recruited to the rehabilitation trial.
2. Elbow study: 21 participants were recruited to the cross-sectional study, 12 patients with RA and 9 healthy participants. These 12 patients participated in the rehabilitation study.

Participant type(s)

Patient

Age group

Not Specified

Sex

Both

Target number of participants

133

Key exclusion criteria

Does not match inclusion criteria

Date of first enrolment

01/04/1996

Date of final enrolment

01/07/1999

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Physiotherapy Division

London

United Kingdom

SE22 8PT

Sponsor information

Organisation

Record Provided by the NHS R&D 'Time-Limited' National Programme Register - Department of Health (UK)

Sponsor details

The Department of Health

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

Sponsor type

Government

Website

<http://www.doh.gov.uk>

Funder(s)

Funder type

Government

Funder Name

NHS Physical and Complex Disabilities National Research and Development Programme (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	01/02/2002		Yes	No