

The Effect of Exercise Training and Psychological Support in Patients With Small Vessel Vasculitis: a Randomised Crossover Study

Submission date 30/09/2004	Recruitment status Stopped	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/09/2004	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 19/05/2008	Condition category Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0265134386

Study information

Scientific Title

Study objectives

Exercise training and psychological support is beneficial in improving health status and exercise capacity in patients with vasculitis.

1. What are the effects on exercise tolerance and health status of an 8 week programme of exercise training in patients with vasculitis?
2. What are the effects of an 8 week programme of psychological support on psychological profile and health status in patients with vasculitis?
3. Is there a difference in efficacy between exercise training and psychological support in terms of improvement in health status and compliance with the intervention?
4. Is there an additive effect of successively combining both treatments and does the order in which these are administered affect the magnitude of the response?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised Crossover Study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

Health condition(s) or problem(s) studied

Cardiovascular: Vasculitis

Interventions

Patients with vasculitis will be recruited to the study and randomly assigned to two groups. Each group will be randomised to receive an 8 week programme of either exercise training or psychological support following which they will crossover and receive the alternative treatment for a further period of 8 weeks. All patients will undergo a 4 week run in period during which time measurements will be made of lung function, exercise capacity, respiratory muscle

function, health status and psychological functioning. These measurements will be repeated at the end of the first period of the crossover study (after 8 weeks) and completion of the second period of the study (after 16 weeks). Of these parameters regular measurement of lung function and respiratory muscle function constitute a part of normal clinical practice.

Each intervention (exercise training and psychological support) will be conducted over a period of weeks and patients will be required to attend the hospital on a weekly basis for a period of approximately one and a half hours for psychological support and twice weekly for exercise training sessions.

As of May 2008, please note that the study was never initiated.

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

28/11/2003

Completion date

28/11/2008

Reason abandoned (if study stopped)

Study was never initiated

Eligibility

Key inclusion criteria

It is proposed to recruit approximately 46 patients (as per sample size calculation) with vasculitis from those attending the Renal Department under Professor Savage/Dr Harper. All patients will have been diagnosed with vasculitis attributable to a range of disorders including microscopic polyangitis, Wegeners granulomatosis, and Churg Strauss syndrome.

The patients recruited to the study will, as far as possible, be equal in numbers of male and female participants and all will be ambulatory.

All patients will undergo a medical examination before being enrolled into the study in order to assess their suitability for maximal exercise testing and training.

Patients receiving a range of medications including oral corticosteroids and immunosuppressants will be included in the study. Use of breathing medication such as

bronchodilators will also be permitted. Patients receiving (or having received in the preceding 6 weeks) antibiotics for a respiratory tract infection will not be enrolled onto the study until they are deemed clinically stable.

During the study, any deterioration in clinical status will be evaluated by the clinical team and the decision on whether to withdraw the patient will then be made. Patients will also be aware that they are free to withdraw from the study at any time without giving prior notice.

Participant type(s)

Patient

Age group

Not Specified

Sex

Both

Target number of participants

46

Key exclusion criteria

1. Any subject with orthopaedic problems preventing exercise or primary cardiac disorders will be excluded from the study.
2. Female patients will be excluded if they are pregnant.

Date of first enrolment

28/11/2003

Date of final enrolment

28/11/2008

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

Selly Oak Hospital

Birmingham

United Kingdom

B29 6JD

Sponsor information

Organisation

Department of Health

Sponsor details

Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type

Government

Website

<http://www.dh.gov.uk/Home/fs/en>

Funder(s)**Funder type**

Government

Funder Name

University Hospital Birmingham NHS Trust (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