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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

Registration date
30/09/2004

Overall study status
Stopped

Last Edited
19/05/2008

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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

Protocol serial number
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

Study type(s)
Not Specified

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(s)
Not provided at time of registration

Key secondary outcome(s))
Not provided at time of registration

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

Healthy volunteers allowed
No

Age group
Not Specified

Sex
All

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
United Kingdom

England

Study participating centre
Selly Oak Hospital
Birmingham
United Kingdom
B29 6JD

Sponsor information

Organisation
Department of Health

Funder(s)

Funder type
Government

Funder Name
University Hospital Birmingham NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration