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Effect of a multidisciplinary in-patient rehabilitation program for patients with ankylosing spondylitis: a randomised controlled trial

Submission date
13/02/2006

Recruitment status
No longer recruiting

Registration date
25/05/2006

Overall study status
Completed

Last Edited
03/05/2019

Condition category
Musculoskeletal Diseases

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

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
N/A

Study information

Scientific Title
Effect of a multidisciplinary in-patient rehabilitation program for patients with ankylosing spondylitis: a randomised controlled trial

Study objectives
Although treatment of patients with ankylosing spondylitis (AS) frequently includes exercise therapies and multidisciplinary interventions, there is a lack of high quality studies that examine the effect of such programs. This study is aimed at evaluating the effect of a multidisciplinary in-patient rehabilitation program compared to community-based standard physiotherapy for patients with AS.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical approval was obtained in 2005 from the Regional Ethical Committee (ref. 738-05259 1.2005.2256), and approval from the Data Inspectorate is in progress as of 13/02/2006.

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Ankylosing spondylitis (AS)

Interventions
The study is a prospective, randomised, controlled (two arm) trial. The two groups are:
1. A three-week multidisciplinary in-patient rehabilitation program
2. Standard community-based physiotherapy

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
1. Physical function, measured by the Bath ankylosing spondylitis functional index (BASFI)
2. Pain, stiffness, fatigue and disease activity: Bath ankylosing spondylitis disease activity index (BASDAI)

Key secondary outcome(s))
1. Self-efficacy: the Arthritis Self-Efficacy Scale (ASES)
2. General health: the Short Form-36 and the BAS Patient Global Score (BAS-G)3. Joint mobility: BAS Metrology Index (BASMI)

4. Biological signs of inflammation: erythrocyte sedimentation rate and C-reactive protein
5. Activity and participation: the Canadian Occupational Performance Measure (COPM)
6. Sleep quality: the Pittsburgh Sleep Quality Index
7. Fatigue: BASDAI, SF-36 (vitality scale) and the Multidimensional Fatigue Inventory
8. Use of medications and health care resources

Completion date
31/12/2008

Eligibility

Key inclusion criteria
1. Aged between 18 and 65 years
2. AS according to the New York classification criteria
3. Ability to communicate in Norwegian

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
95

Key exclusion criteria
1. Coronary heart disease
2. Surgery or rehabilitation last six months
3. Cognitive impairment or mental disease
4. Pregnancy
5. Change in medication last month
6. BASDAI score <40 mm

Date of first enrolment
01/01/2006

Date of final enrolment
31/12/2008

Locations

Countries of recruitment
Norway

Study participating centre
National Resource Center for Rehabilitation in Rheumatology
Oslo
Norway
0319

Sponsor information

Organisation
The Norwegian Government (Helse Øst)

ROR
https://ror.org/02qx2s478

Funder(s)

Funder type
Government

Funder Name
Norwegian government - Helse Øst (Health East)

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	01/03/2013	03/05/2019	Yes	No