

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	<input type="checkbox"/> Prospectively registered
Registration date 25/05/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 03/05/2019	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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

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 measure

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)

Secondary outcome measures

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

Overall study start date

01/01/2006

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

100

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)

Sponsor details

Pb 404

Hamar

Norway

2303

+47 (0)62 58 55 00

postmottak@helse-ost.no

Sponsor type

Government

Website

<http://www.helse-ost.no>

ROR

<https://ror.org/02qx2s478>

Funder(s)

Funder type

Government

Funder Name

Norwegian government - Helse Øst (Health East)

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