# Alendronate in ankylosing spondylitis trial

Submission date 02/12/2015	<b>Recruitment status</b> No longer recruiting
Registration date 15/12/2015	<b>Overall study status</b> Completed
Last Edited 13/01/2017	<b>Condition category</b> Musculoskeletal Diseases

Prospectively registered

- [] Protocol
- [] Statistical analysis plan
- [X] Results
- [] Individual participant data

### **Plain English Summary**

Background and study aims

Ankylosing spondylitis (AS) is a long-term condition in which the spine becomes inflamed. It is usually treated with anti-inflammatory drugs, but they do not reduce the rate of disease progression. Patients with AS have reduced bone density of the spine and hip and are at increased risk of fractures of the spine. Such microfractures may be responsible for pain in AS. Studies using a drug called pamidronate, which belongs to a group of drugs know as bisphosphonates, given into a vein have suggested these drugs may improve the clinical features of AS. An oral form of a bisphosphonate, called alendronate, is used to treat osteoporosis. The aim of this study is to see if alendronate improves outcomes in patients with AS over a 2 year period when compared to a placebo (dummy drug).

Who can participate? Patients aged over 21 with AS.

What does the study involve?

Participants are randomly allocated to be treated weekly with either oral alendronate or a placebo (dummy drug). We then study the disease outcome and the effects on bone density.

What are the possible benefits and risks of participating? Alendronate may improve disease activity in AS. The risks are possible upper gastrointestinal (digestive system) side effects, arthralgia (joint pain), and rare complications of osteonecrosis (bone disease) of the jaw.

Where is the study run from? Royal National Hospital for Rheumatic Diseases (UK).

When is the study starting and how long is it expected to run for? May 2004 to August 2010.

Who is funding the study? Arthritis Research UK and the National Ankylosing Spondylitis Society.

Who is the main contact? Dr Ashok Bhalla

# **Contact information**

**Type(s)** Scientific

**Contact name** Dr Ashok Bhalla

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**Contact details** Royal National Hospital for Rheumatic Diseases Bath United Kingdom BA1 1RL

# Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

### Secondary identifying numbers

BSR / Arthritis Research UK project grant (14585)

# Study information

### Scientific Title

Clinical efficacy of oral alendronate in ankylosing spondylitis: a randomised placebo-controlled trial

Acronym

BIAS (Bisphosphonates in Anklyosing Spondylitis)

### Study hypothesis

To investigate the potential disease modifying properties of alendronate in a population of ankylosing spondylitis (AS) patients with a spectrum of mild to severe disease activity, reflecting routine clinical practice.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

- 1. Trent MREC, 10/05/2004, REC ref: 04/4/023
- 2. Site-specific approval was obtained from the all UK recruiting centres

**Study design** Double-blind randomised controlled trial

**Primary study design** Interventional

**Secondary study design** Randomised controlled trial

**Study setting(s)** Hospital

**Study type(s)** Treatment

#### Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

**Condition** Ankylosing spondylitis

#### Interventions

Oral alendronate 70 mg weekly or placebo

The total duration of treatment was 2 years and follow-up for all treatment arms was 2 years from enrolment.

Intervention Type

Drug

**Phase** Phase I

Drug/device/biological/vaccine name(s)

Alendronic acid

#### Primary outcome measure

Bath Ankylosing Spondylitis Global score (BAS-G), assessing overall change in patient's symptoms and general health over the preceding month. Scored at baseline, 3, 6, 12, 18 and 24 months

#### Secondary outcome measures

1. Disease activity (Bath AS Disease Activity Index (BASDAI) scored at baseline, 3, 6, 12, 18 and 24 months

2. Physical function (Bath AS Functional Index (BASFI) scored at baseline, 3, 6, 12, 18 and 24 months

3. Mobility (Bath AS Metrology Index (BASMI) measured at baseline and 24 months

4. Laboratory measurements:

4.1. At baseline and 6 months blood was taken for measurement of cytokines and metalloproteinases

4.2. The inflammation marker, CRP, was measured at baseline, 3, 6, 12 and 24 months
5. Radiographic features were assessed by modified Stoke Ankylosing Spondylitis Spinal Score (mSASSS) and Bath AS Radiology Index (BASRI) at 0 and 24 months
6. Assessment in SpondyloArthritis international Society (ASAS) 20 and ASAS40 at 0 and 24 months

### Overall study start date

01/05/2004

## Overall study end date

30/08/2010

# Eligibility

#### Participant inclusion criteria

1. Patients had to meet the modified New York criteria for the diagnosis of AS, which we refined to allow for MRI diagnosis of sacroiliitis, and a requirement for a minimum pre-defined movement restriction

2. Fulfil ASAS criteria for axial SpA

3. Aged over 21 years

4. If taking NSAID, have been on a stable dose for at least 4 weeks

5. There was no minimal level of disease activity required for entry to the study

#### Participant type(s)

Patient

#### Age group

Adult

#### Sex

Both

#### Target number of participants

The study was powered to detect a minimal clinically important difference of 1.5 in the primary outcome measure (BAS-G). With 95% power to reach 5% level of significance this required a total sample size of 140 (70 in each group). Assuming a 20% dropout rate, 90 patients were required in each group to obtain a sample size of 70.

#### Participant exclusion criteria

1. Any intervention or underlying disease with the potential to effect disease activity or bone density, including treatment with anti-TNF

2. Patients with bilateral hip replacements or previous back surgery that would prevent accurate bone density measurement by dual x-ray absorptiometry (DXA)

#### **Recruitment start date**

01/05/2005

### Recruitment end date

28/02/2009

# Locations

**Countries of recruitment** England

United Kingdom

**Study participating centre Royal National Hospital for Rheumatic Diseases** Upper Borough Walls Bath United Kingdom BA1 1RL

# Sponsor information

**Organisation** Royal National Hospital for Rheumatic Diseases (UK)

**Sponsor details** Upper Borough Walls Bath England United Kingdom BA1 1RL

**Sponsor type** Hospital/treatment centre

ROR https://ror.org/05va5gy74

# Funder(s)

Funder type Charity

**Funder Name** Arthritis Research UK (BSR/Arthritis Research UK Project Grant (14585))

Alternative Name(s)

**Funding Body Type** Private sector organisation

**Funding Body Subtype** Other non-profit organizations

**Location** United Kingdom

**Funder Name** National Ankylosing Spondylitis Society

# **Results and Publications**

#### Publication and dissemination plan

The plans were to present results at national meeting of the British Society for Rheumatology (BSR) and publish in peer-reviewed journal.

Intention to publish date

Individual participant data (IPD) sharing plan

#### IPD sharing plan summary

Available on request

#### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2017		Yes	No