ISRCTN73579020 https://doi.org/10.1186/ISRCTN73579020

# BOSSA Study: Bosentan for the treatment of Steroid-resistant Pulmonary Sarcoidosis

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 31/08/2010 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 27/09/2010 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 01/11/2018 | Haematological Disorders | |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

**Contact name**
Prof Michael Tamm

**Contact details**
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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
N/A

## Study information

**Scientific Title**

Randomised placebo-controlled, double-blind, exploratory trial of Bosentan for Steroid-resistant Pulmonary Sarcoidosis: the BOSSA Study

## Acronym
BOSSA

## Study objectives
To assess the safety and efficacy of a treatment with bosentan in steroid-resistant sarcoidosis.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
The Ethics Committee of University Hospital Basel approved on the 29th May 2007 (ref: Nr. 71 /07)

## Study design
Randomised placebo controlled phase II study

## 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 contact details below to request a patient information sheet

## Health condition(s) or problem(s) studied
Sarcoidosis with pulmonary involvement

## Interventions
Patients will be randomised to receive
1. Bosentan
2. Placebo
62.5 mg Twice daily (BID) for 4 weeks followed by 125 mg BID for 11 months.

## Intervention Type
Drug

## Phase
Phase II

### Drug/device/biological/vaccine name(s)
Bosentan

### Primary outcome measure
1. Safety as measured by severe adverse events (SAEs) and necessity to stop bosentan due to increases liver enzymes
2. Efficacy at 12 months as measured by:
2.1. Overall response rate as defined by a 10% improvement of either TLC, DLCO, VO2 peak, endurance time at 75% of VO2 peak or 6-min walk distance (6MWD)
or
2.2. A decrease in the HRCT-score greater than or equal to and absence of worsening by at least 10% in any functional parameters and absence of an increase in the HRCT-score greater than or equal to 2

### Secondary outcome measures
1. Overall adverse events, reported during the regular visits of the patients at the centres
2. Changes in QoL, measured by SF-36 questionnaire
3. Decrease in expression of genes associated with firbroproliferation
4. Efficacy at 3, 6 and 9 months

### Overall study start date
01/10/2007

### Completion date
31/12/2012

## Eligibility

### Key inclusion criteria
1. Biopsy-proven sarcoidosis with pulmonary involvement stages II, III, (IV) according to Silzbach
2. Persistant symptoms on long-term oral corticosteroids (greater than 2 months; 5 mg prednisone or equivalent and/or other immunosuppressive agents
3. Aged greater than 18 years
4. Informed written consent
5. Impaired exercise capacity (oxygen uptake [VO2] peak less than 80%) or resting lung functions (forced expiratory volume in one second [FEV1], forced vital capacity [FVC] or diffusing capacity of the lung for carbon monoxide [DLCO] less than 80%)

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
36

### Key exclusion criteria
1. Systemic illness other than sarcoidosis requiring immunosuppressive therapy
2. Honey combing greater than 10% on High Resolution Computed Tomography [HRCT] scan
3. Marked disturbance of liver enzymes at baseline
4. Pregnancy
5. Relevant psychiatric illness or addictive disorder
6. Previous or current treatment with bosentan
7. Therapry with cyclosporine A

### Date of first enrolment
01/10/2007

### Date of final enrolment
31/12/2012

## Locations

### Countries of recruitment
Switzerland

### Study participating centre
**University Hospital Basel**
Basel
Switzerland
4031

## Sponsor information

### Organisation
University Hospital Basel (Switzerland)

### Sponsor details
c/o Prof. Michael Tamm
Petersgraben 4
Basel
Switzerland
4031

### Sponsor type
Hospital/treatment centre

### Website

http://www.unispital-basel.ch/

**ROR**
https://ror.org/04k51q396

# Funder(s)

**Funder type**
Industry

**Funder Name**
Actelion Pharma Schweiz AG (Germany)

# 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 | 28/10/2018 | | Yes | No |