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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

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Additional identifiers

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

Study type(s)
Treatment

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(s)
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

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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)

ROR
https://ror.org/04k51q396

Funder(s)

Funder type
Industry

Funder Name
Actelion Pharma Schweiz AG (Germany)

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	28/10/2018		Yes	No