

Trial Description

Title

Influence of inhaled Aviptadil on the immunologic activity of alveolar macrophages in sarcoidosis

Trial Acronym

AVISARCO

URL of the trial

[---]*

Brief Summary in Lay Language

Patients with histologically proven sarcoidosis and active disease by clinical judgement are eligible for inclusion in this study. The aim of the study is to test whether a short treatment period with Aviptadil inhalation changes cellular responses in the lung. Therefore, patients will receive Aviptadil by inhalation. Aviptadil is synthetically produced vasoactive intestinal peptide (VIP). VIP is naturally occurring neuropeptide of the human body. In animal and in vitro experiments it was shown that VIP changes the immune response and thereby influences disease processes.

Brief Summary in Scientific Language

Patients with histologically proven active pulmonary sarcoidosis were included in the study evaluating the inhalative Aviptadil (synthetic vasoactive intestinal peptide, VIP). The patients will receive 50 µg synthetic VIP (Aviptadil, mondoBIOTECH) four times daily by inhalation via an ultrasonic nebulizer (Optineb®, Nebu-Tec, Elsenfeld, Germany) for 28 days. At day 1, before the first inhalation of VIP, vital signs, pulmonary function, CO diffusion capacity, laboratory chemistry and bronchoalveolar lavage will be obtained. After that, the patients will be advised in detail about the inhalation method and will receive the study medication. The baseline procedures of day 0 will be repeated at the end of treatment period. BAL cell differential counts will be obtained. In addition, BAL cell cytokine production and surface marker expression will be analyzed by ELISA and flow cytometry.

Organizational Data

- DRKS-ID: **DRKS00000184**
- Date of Registration in DRKS: **2009/08/19**
- Date of Registration in Partner Registry or other Primary Registry: **2005/04/19**
- Investigator Sponsored/Initiated Trial (IST/IIT): **no**
-

DRKS-ID: **DRKS00000184**

Date of Registration in DRKS: **2009/08/19**

Date of Registration in Partner Registry or other Primary Registry:
2005/04/19

DRKS-ID: **DRKS00000184**

Date of Registration in DRKS: **2009/08/19**

Date of Registration in Partner Registry or other Primary Registry: **2005/04/19**

Investigator Sponsored/Initiated Trial (IST/IIT): **no**

Ethics Approval/Approval of the Ethics Committee: **Approved**

- (leading) Ethics Committee Nr.: **178/04 , Ethik-Kommission der Albert-Ludwigs-Universität Freiburg**

Secondary IDs

- EudraCT-No.
(for studies acc. to Drug Law): **2004-003759-38**
- Partner Registry-ID: **UKF000356 (Register Klinischer Studien des Universitätsklinikums Freiburg)**

Health condition or Problem studied

- ICD10: **D86.0 - Sarcoidosis of lung**

Interventions/Observational Groups

- Arm 1: **open, uncontrolled; 50 microgramm Aviptadil four times daily per inhalation**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Single arm study**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Uncontrolled/Single arm**
- Purpose: **Treatment**
- Assignment: **Single (group)**
- Phase: **II**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

Spontaneous production of TNF-alpha by BAL cells

Secondary Outcome

- a) changes in TGF beta1, TGF beta2, IL-2, IL-4, IL-5, IL-6, IL-8, IL-10 and IFN-gamma; expression in alveolar macrophages;
- b) changes in the expression of the CD1a, CD1c, CD11a, CD11b, CD11c, CD18, CD20, CD40, CD54, CD58, CD68, CD80, CD83, CD86, CD123, HLA-DR cell surface marker of the alveolar macrophages of sarcoidosis patients;
- c) changes in the quality of life as recorded in appropriate questionnaire forms (SF36, EuroQol, St. George's Respiratory Questionnaire)
- d) clinical deterioration;
- e) Safety parameters
 - * Vital signs
 - * Body weight
 - * Tolerance

Countries of recruitment

- DE **Germany**

Locations of Recruitment

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2006/05/29**
- Target Sample Size: **30**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **80 Years**

Additional Inclusion Criteria

Diagnosis: clinically active pulmonary sarcoidosis, with or without ocular sarcoidosis based on clinical history, and lung or intrathoracic lymph node biopsy, consistent with sarcoidosis with other causes of granuloma ruled out

***Aged above 18 years**

***Written consent**

***Adequate contraception in female patients of childbearing age**

***Negative pregnancy test**

Exclusion criteria

***Lack of consent**

***Pregnancy and lactation**

***Presumed non-cooperativeness**

***Patients outside the stipulated age range**

***Malignant diseases in anamnesis**

***Legal incapacity**

***Parallel participation in another clinical trial**

***Clinical instability**

***Abnormal breathing**

Addresses

■ Primary Sponsor

**mondoBIOTECH Laboratories Anstalt
mondoBIOTECH
Austrasse 79, Europapark
9490 Vaduz
Switzerland**

Telephone: ++**41 91 986 4939**

Fax: ++**41 91 986 4930**

E-mail: **info at mondobiotech.com**

URL: [---]*

■ Contact for Scientific Queries

**Universitätsklinikum Freiburg, Abteilung für Pneumologie
Ms. Dr. med. Antje Prasse
Killianstrasse 5
79106 Freiburg
Germany**

Telephone: ++**49 (0)761 2703720**

Fax: ++**49 (0)761 2703704**

E-mail: **antje.prasse at uniklinik-freiburg.de**

URL: **http://www.uniklinik-freiburg.de/pneumologie/live/index.html**

■ Contact for Public Queries

**Universitätsklinikum Freiburg, Abteilung für Pneumologie
Mr. Prof. Dr. med. Joachim Müller-Quernheim**

Contact for Public Queries

Universitätsklinikum Freiburg, Abteilung für Pneumologie
Mr. Prof. Dr. med. Joachim Müller-Quernheim
Killianstrasse 5
79106 Freiburg
Germany

Telephone: ++49 (0)761 2703706

Fax: ++49 (0)761 2703704

E-mail: [joachim.mueller-quernheim at uniklinik-freiburg.de](mailto:joachim.mueller-quernheim@uniklinik-freiburg.de)

URL: <http://www.uniklinik-freiburg.de/pneumologie/live/index.html>

Sources of Monetary or Material Support

■ Commercial (pharmaceutical industry, medical engineering industry, etc.)

mondoBIOTECH Laboratories Anstalt
Austrasse 79, Europapark
9490 Vaduz
Switzerland

Telephone: ++41 91 986 4939

Fax: ++41 91 986 4930

E-mail: [info at mondobiotech.com](mailto:info@mondobiotech.com)

URL: [---]*

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2009/09/30**

Trial Publications, Results and other documents

- Paper **Prasse A, Zissel G, Lutzen N, Schupp J, Schmiedlin R, Gonzalez-Rey E, Rensing-Ehl A, Bacher G, Cavalli V, Bevec D, Delgado M, Muller-Quernheim J. Inhaled vasoactive intestinal peptide exerts immunoregulatory effects in sarcoidosis. Am J Respir Crit Care Med. 2010 Aug 15;182(4):540-8.**

* This entry means the parameter is not applicable or has not been set.

*** This entry means that data is not displayed due to insufficient data privacy clearing.