PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

Phase III, multi-center, randomized, double-blind, placebo-controlled study for treatment of juvenile ankylosing spondylitis with Adalimumab

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

**This study aims at patients with juvenile ankylosing spondylitis (M. Bechterew), who did not respond to therapy with nonsteroidal anti-inflammatory drugs.
The TNF inhibitor Adalimumab is approved in the therapy of ankylosing spondylitis in adult patients, the treatment requires a subcutaneous injection of Adalimumab every other week.
This study designed to evaluate the efficacy and safety of treatment of juvenile ankylosing spondylitis with adalimumab.
In the first 12 week period patients will receive either Adalimumab or placebo, in the following 12 week period all patients will receive Adalimumab and can possibly profit from treatment.
During the study monthly visits at the study centre are required.**

Brief Summary in Scientific Language

**This randomized, double-blind, placebocontrolled study is designed to assess efficacy and safety of treatment of juvenile ankylosing spondylitis with Adalimumab, a TNF inhibitor. In the therapy of ankylosing spondylitis in adult patients Adalimumab has been shown to be effective and is already approved.
Study design: In the first placebo-controlled 12 week period subjects who meet all entry criteria will be randomized to either 40 mg Adalimumab or placebo injected subcutaneously every other week. In the following 12 week period all patients will receive 40mg of Adalimumab subcutaneously every other week.
Physical examinations, measures of disease activity and laboratory tests are to be performed at screening, baseline and every 4 weeks.**

Organizational Data

- DRKS-ID: **DRKS00000071**
- Date of Registration in DRKS: **2009/02/06**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***

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Date of Registration in DRKS: **2009/02/06**
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- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **2008035 , Ethikkommission der Ärztekammer Nordrhein**

Secondary IDs

- EudraCT-Number: **2007-003358-27**
- PEI-No.: **544/01**

Health condition or Problem studied

- Free text: **juvenile ankylosing spondylitis**
- ICD10: **M08.1 - Juvenile ankylosing spondylitis**

Interventions/Observational Groups

- Arm 1: **Adalimumab 40mg s.c. every other week**
- Arm 2: **Placebo s.c. every other week**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **Double or multiple blind**
- Who is blinded: **[---]***
- Control: **Placebo**
- Purpose: **Other**
- Assignment: **Parallel**
- Phase: **III**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

- to demonstrate the superiority of adalimumab with respect to the ASAS Working Group response criterion ASAS40 as compared to placebo
- to contrast the safety profile of adalimumab with placebo in subjects with juvenile ankylosing spondylitis.

Secondary Outcome

- to show improvement of each of the 4 categories contributing to the ASAS40 criterion (spinal inflammation, back pain, patient's global assessment, physical function)
- to show superiority of adalimumab with respect to the ACR Ped 30 response criterion as compared to placebo
- to show improvement of each of the 6 categories contributing to the ACR Ped Score (physician's global assessment, parents' global assessment of subject's overall well-being, number of active joints, number of joints with limitation of motion, physical function, CRP).

Countries of recruitment

- DE **Germany**

Locations of Recruitment

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2008/07/02**
- Target Sample Size: **50**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **12 Years**
- Maximum Age: **18 Years**

Additional Inclusion Criteria

- IN1 Parents / legal guardian are willing to participate in the study and signed voluntarily the Informed Consent form.

-IN2Parents / legal guardian are willing to actively supervise storage and administration of study drug and to ensure that the time of each dose is accurately recorded in the subject's diary.

-IN3Patient and parents / legal guardian agree to comply with study requirements and are able to be at the clinic for all required study visits.

-IN4Patient is at least 12 years old and has not reached his 18th birthday.

-IN5The weight of the patient is > 30 kg.

-IN6IN FEMALE PATIENT IN WHOM MENARCHE HAS OCCURRED

>Negative serum pregnancy test prior to administration of study medication.

Exclusion criteria

- **EX1 Patient has been diagnosed to have systemic onset of JRA / JIA or has active systemic features including fever or rash.**
- **EX2 Patient has active uveitis within a period of 4 weeks prior to the**

first administration of study medication.

-EX3Pregnant or breast feeding female.

-EX4Female not willing to use appropriate contraception or sexual abstinence.

-EX5Chronic or active infectious disease, especially patient is positive for the hepatitis B surface antigen.

-EX6Preceding severe infectious disease during a period of 3 months prior to the first administration of study medication.

-EX7Preceding diagnosis of tuberculosis or any opportunistic infection including herpes zoster at any time.

-EX8Any preceding diagnosis of malignancy.

-EX9Patient has a history of any chronic disease other than JAS, JRA / JIA,

-EX20Demonstration of clinically significant deviations in any of the following

laboratory parameters:

>platelet count < 100.000/mm3

>total white cell count < 4000 cells/mm3

>neutrophils < 1000 cells/mm3

>hematocrit < or = 24%

>AST or ALT or serum bilirubin > 2x the upper limit of normal

>glomerular filtration rate GFR < 90 mL/min / 1.73 m2 BSA

Addresses

- **Primary Sponsor**

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Sources of Monetary or Material Support

- **Commercial (pharmaceutical industry, medical engineering industry, etc.)**

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Germany

Telephone: **06112 580**
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

Status

- Recruitment Status: **Recruiting stopped after recruiting started**
- Study Closing (LPLV): **2011/03/24**

Trial Publications, Results and other documents

■ Abstract **Abstract**

** 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.*