Trial Description

Title

A prospective, monocentric clinical trial with adalimumab for topical treatment in chronic wounds

Trial Acronym

ADATOP

URL of the trial

[---]*

Brief Summary in Lay Language

Various therapeutic options were used in the former treatment of subjects without healing up. In ADATOP Adalimumab apply in area of the wound external only (so-called topic application). We hope that the clinical trial can improve wound healing, so wound closure could be possible.

Brief Summary in Scientific Language

In this trial we will research the possible influence of wound healing by topic application of adalimumab weekly over maximal 8 weeks in chronic wounds without any other option of treatment.

Organizational Data

- DRKS-ID: **DRKS00000583**
- Date of Registration in DRKS: **2010/11/03**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **269-08 , Ethikkommission an der Medizinischen Fakultät der Universität Leipzig**

Secondary IDs

- EudraCT-No.
  (for studies acc. to Drug Law): **2009-015749-22**
- PEI-No.: **1183/01**

Health condition or Problem studied

- ICD10: **L97 - Ulcer of lower limb, not elsewhere classified**
- ICD10: **[---]* - [---]***

Interventions/Observational Groups

- Arm 1: **topic application of adalimumab weekly over maximal 8 weeks**

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

percental reduction of wound area under serial treatment with Adalimumab, measurement by fotographical documentation and measurement of the wound

Secondary Outcome

- occurrence of new or aggravation of existent infection
- pain associated with chronic wound
- occurrence of possible contraindications

Countries of recruitment

- DE **Germany**

Locations of Recruitment

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2011/08/12**
- Target Sample Size: **18**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **50 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

- at least one chronic wound without signs of infection. At the time point of study inclusion the wound must measure between 2,25 cm2 and 64 cm2.
- age ≥50 years
- at least 6 months existence without significant recovery although optimal wound care
- written informed consent

Exclusion criteria

- pregnancy and nursing women,
- presence of severe hepatic insufficiency or renal insufficiency
- presence of hepatitis
- chronic severe focus of infection
- severe wound infection
- known hypersensitivity to Adalimumab or other components of IMP
- signs of latent or active tuberculosis
- clinically decompensated heart failure (NYHA III/IV),
- inusfficient compliance
- active demyelinating or other neurological disorder
- malignant or lymphoproliferative disorder
- known autoimmune disorder
- intake of other immunodepressive drugs
- women of child bearing potential (< 2 years after last menstruation)
- concurrent participation in other clinical trials
- persons dependent on investigator

Addresses

■ **Primary Sponsor**

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■ **Contact for Scientific Queries**

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Sources of Monetary or Material Support

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

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65205 Wiesbaden-Delkenheim

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65205 Wiesbaden-Delkenheim
Germany

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

Status

- Recruitment Status: **Recruiting stopped after recruiting started**
- Study Closing (LPLV): **2012/06/29**

Trial Publications, Results and other documents

** 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.*