

Trial Description

Title

Gene expression profiling of angiogenic factors in osteonecrosis of the jaw

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

The cause for the osteonecrosis of the jaw is not only a problem of acute or chronic infection but also a matter of impaired blood circulation in the affected area. The reason and the biological interactions of this development are not fully understood so far.

With standard laboratory procedures this study analyses the alterations of the genes that organize the formation and the proliferation of the vessel system. The bone samples are taken from patients suffering from osteonecrosis, the genetic information will be extracted from these samples.

With this fundamental knowledge the diagnosis and finally the therapy of this disorder will be improved.

Brief Summary in Scientific Language

One relevant aspect of the development of the chronic necrosis of the jaw is the impaired vascularisation. The relevant pathologies are the chronic infection of the jaw, the osteoradionecrosis and the bisphosphonate associated necrosis of the jaw. Their therapy so far consists in the administration of antibiotics and/or the surgical resection of the affected areas. The genetic alterations that lead to a reduction of the local blood circulation are not clear to date.

Our aim is the targeted detection and interpretation of the genetic alterations of genes closely related to angiogenesis with the help of a combination of the preparation of functional RNA and the genome array analysis.

The profiling of transcripts is a useful tool to unmask characteristic alterations in the angiogenic pathway.

Due to the severity and the progressive course of these diseases new strategies in diagnosis and therapy are mandatory with special regard to the impaired vascularisation.

In the long run we will re-define the diagnosis and classification of this illness on the basis of our findings and provide a basis to develop an innovative treatment regimen.

Organizational Data

■ DRKS-ID: **DRKS00000728**

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Date of Registration in DRKS: **2011/04/28**

- 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.: **2010-462-f-S , Ethik-Kommission der Ärztekammer Westfalen-Lippe und der med. Fakultät der Westfälischen Wilhelms-Universität Münster**

Secondary IDs

Health condition or Problem studied

- Free text: **Osoteonecrosis of the jaw**
- ICD10: **K10.28 - [generalization K10.2: Inflammatory conditions of jaws]**

Interventions/Observational Groups

- Arm 1: **Observation Group
gene expression analysis (microarray) of bone tissue**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Other**
- Allocation: **Single arm study**
- Blinding: **Open (masking not used)**
- Who is blinded: [---]*
- Control: **Uncontrolled/Single arm**
- Purpose: **Basic research/physiological study**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): [---]*

Primary Outcome

what: performance of the genome arrays by microarray technique: Identification of significantly altered gene expression profile in the angiogenic pathway
when: october 2012
how: statistical analysis, clinical evaluation and correlation

Secondary Outcome

what: collection of RNA samples
when: april 2012
how: storage of a RNA database

Countries of recruitment

- **DE Germany**

Locations of Recruitment

Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2011/06/01**
- Target Sample Size: **90**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

histologically diagnosed osteomyelitis radionecrosis or bisphosphonate associated osteonecrosis of the jaw, informed consent, 18 years or older, operability

Exclusion criteria

younger than 18 years, no informed consent, no histologically confirmed diagnosis

Addresses

■ Primary Sponsor

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■ Contact for Scientific Queries

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Sources of Monetary or Material Support

■ Institutional budget , no external funding (budget of sponsor/PI)

Klinik und Poliklinik für Mund- und Kiefer-Gesichtschirurgie

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Deutsches Register
Klinischer Studien

German Clinical
Trials Register

Institutional budget , no external funding (budget of sponsor/PI)

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URL: [---]*

Status

- Recruitment Status: **Recruiting planned**
- Study Closing (LPLV): [---]*

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.