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

Trial Description

Title

Sequential activation of the AKT pathway in human osteoblasts treated with Oscarvit: a bioactive product with positive effect both on skeletal pain and mineralization in osteoblasts

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

The aims of the study are: (i) to prove a possible positive effect of oscarvit (OSC) on patient's bone pain, (ii) to analyse the effect of OSC on the expression of osteoblast-specific genes and proteins which play an important role in bone development, (iii) to measure the effect of OSC on calcium content in osteoblasts, and (iiii) to analyse whether OSC has any influence on signal transduction pathways in osteoblasts.

Brief Summary in Scientific Language

**Oscarvit (OSC) is an in-house preparation consisting of minerals and naturally occurring glycosaminoglycans. OSC has been used to analyze its effect on pain associated with bone diseases and in vitro in osteoblasts.
OSC, 0.6 g three times daily, resulted in significant positive effect on pain alleviation of 68% after 20 days. In in-vitro cultivated osteoblasts significant overexpression of osteocalcin, osteopontin , bone sialoprotein, and dentin matrix phosphoprotein genes could be detected when compared to control osteoblasts. OSC-treated osteoblasts produced vast extracellular calcium deposits. In addition OSC promotes osteoblasts differentiation and activates the AKT signaling pathway.**

Do you plan to share individual participant data with other researchers?

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00013233**
- Date of Registration in DRKS: **2017/11/06**
- 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.: **D475/14 , Ethikkommission der Christian-Albrechts-Universität zu Kiel**

Secondary IDs

Health condition or Problem studied

- ICD10: **M80 - Osteoporosis with pathological fracture**
- ICD10: **M81 - Osteoporosis without pathological fracture**
- ICD10: **M82 - Osteoporosis in diseases classified elsewhere**

Interventions/Observational Groups

- Arm 1: **Oscarvit, 3x600 mg/day, for 20 days**

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: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

After 20 days treatment with OSC (3x600mg/day) the alleviation of pain will be measured by questioning of the patients in accordance with Numeric Pain Rating Scale (NPRS).

Secondary Outcome

Additional goal criteria for the study was the evaluation of pain after 5- and 10 days treatment with OSC according to NPRS.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- **Kiel, [---]***

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2014/10/01**
- Target Sample Size: **15**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

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

Additional Inclusion Criteria

The patient is suffering from osteoporoses/osteoarthrosis

Exclusion criteria

There is no participation for patients who are not suffering from osteoporoses/osteoarthrosis

Addresses

■ **Primary Sponsor**

Universitätsklinikum Schleswig Holstein, Hals-,Nasen-,Ohrenklinik, Kopf- und Halschirurgie
Mr. PD. Dr. Tibor Görögh
Arnold-Heller 3, Haus 27
24105 Kiel
Germany

Telephone: **49 (431) 500-21701**
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

■ **Contact for Scientific Queries**

Universitätsklinikum Schleswig-Holstein Hals-,Nasen-,Ohrenklinik, Kopf- und Halschirurgie
Mr. PD. Dr. Tibor Görögh
Arnold-Heller 3, Haus 27,
24105 Kiel
Germany

Telephone: **0049-431-500-21850**
Fax: **[---]***
E-mail: **gorogh at hno.uni-kiel.de**
URL: **[---]***

■ **Contact for Public Queries**

Universitätsklinikum Schleswig-Holstein Hals-,Nasen-,Ohrenklinik, Kopf- und Halschirurgie
Mr. PD. Dr. Tibor Görögh
Arnold-Heller 3, Haus 27,
24105 Kiel
Germany

Telephone: **0049-431-500-21850**
Fax: **[---]***
E-mail: **gorogh at hno.uni-kiel.de**
URL: **[---]***

■ **Collaborator, Other Address**

Universitätsklinikum Schleswig-HolsteinKlinik für Orthopädie und Unfallchirurgie
Mr. PD. Dr. Sebastian Lippross
Arnold-Heller-Straße 3, Haus 18,
24105 Kiel
Germany

Collaborator, Other Address

Universitätsklinikum Schleswig-HolsteinKlinik für Orthopädie und Unfallchirurgie
Mr. PD. Dr. Sebastian Lippross
Arnold-Heller-Straße 3, Haus 18,
24105 Kiel
Germany

Telephone: **49 (431) 500-20827**
Fax: **[---]***
E-mail: **Sebastian.Lippross at uksh.de**
URL: **[---]***

Sources of Monetary or Material Support

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

  Universitätsklinikum Schleswig-Holstein, Hals-,Nasen-,Ohrenklinik, Kopf-und Halschirurgie
  Arnold-Heller 3, Haus 27
  24105 Kiel
  Germany

  Telephone: **[---]***
  Fax: **[---]***
  E-mail: **[---]***
  URL: **[---]***
- **Private sponsorship (foundations, study societies, etc.)**

  Biog
  Mr. PD. Dr. Tibor Görögh,
  Radward 5
  24223 Schwentinental
  Germany

  Telephone: **04307-7542**
  Fax: **[---]***
  E-mail: **goeroegh at t-online.de**
  URL: **[---]***

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2015/04/01**

Trial Publications, Results and other documents

- Trial results **Studienergebnisse**

** 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.*