Trial Description

Title

Effectiveness of leech therapy in treatment of chronic low back pain - a randomised controlled clinical study

Trial Acronym

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URL of the trial

http://naturheilkunde.immanuel.de/forschung/aktuelle-studien/blutegeltherapie-bei-rueckenschmerzen.html

Brief Summary in Lay Language

Testing the effectiveness of a single time leech therapy for chronic low back pain compared to standard back exercises

Brief Summary in Scientific Language

open RCT
intervention
single application of 4 upt 7 leeches in paravertebral L1-S3
control:
mixed back exercise and aerobic nordic walking over 4 weeks 1 hour per week
primary outcome: Reduktion of global low back pain during the last week at day 28 +-3 messured by 100mm VAS
most importan secondary outcomes:
same VAS as above but day 56+-5, questionnaires:
SF-36, FFBH-R, SES, diary for use of pain medication

Organizational Data

- DRKS-ID: **DRKS00004871**
- Date of Registration in DRKS: **2013/04/26**
- Date of Registration in Partner Registry or other Primary Registry: **2012/04/23**
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **11/0576 - ZS EK , Ethik-Kommission des Landes Berlin**

Secondary IDs

- EudraCT-No. (for studies acc. to Drug Law): **2011-004393-28**
- Primary Registry-ID: **2011-004393-28 (EUCTR - European Register for Clinical Trials)**
- BfArM-No.: **4037866**

Health condition or Problem studied

- ICD10: **M54.5 - Low back pain**

Interventions/Observational Groups

- Arm 1: **Leeches (Hirudo verbana), single topical application of 4 to 7 animals, paravertebral L1-S3 (leeching time interindividual variations from ca. 45 up to 90 min until leeches release by themselves)**
- Arm 2: **Back exercise, meaning 1 time a week 1h of mixed workout an aerobic nordic walking**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **data analyst**
- Control: **Active control (effective treament of control group)**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

global back pain on a 100mm VAS (visual analog scale) at day 28+-3

Secondary Outcome

day 0:
• general patients assuming concerning effectivenes and agreeability (Likert

Skala)

day 56±5:
• VAS (100 mm) painscore (backpain)

day 0, 28+-3, 56+-5:
• 100 mm VAS scoring the average disability caused by back pain during the last week
• Roland Morris Disability Questionnaire (RMDQ)
• Functionial Questionarry of Back Pain (FFbH-R)
• Quality of life SF36
• mood, depression (CES-D)
• affective pain assessment (SES)

during whole study period
•intensity/frequency of pain medication (diary)

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Hochschulambulanz für Naturheilkunde, Berlin**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2013/05/02**
- Target Sample Size: **44**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **70 Years**

Additional Inclusion Criteria

-male and femal patient from 18 to 70 years old
-existing, specialised physician (orthopedics, neurology, pain treatment) prooved diagnosis of chronic low back pain caused by nonspecific lumbar syndrome at least since 3 months

- averaged pain intensity during the last 3 month of at least 40mm measured by VAS (visual analog scale) during pain periods on 4 out of 7 days a week

Exclusion criteria

-anticoagulative treatment
-anemia (Hgb in screening-lab below 12.2 g/dl bzw. 7.6 mmol/l (women); 14.0 g/dl bzw. 8.7 mmol/l (men)
-anmenestic or laboratoric tested clotting disorder (Quick <70%, apTT >36 sec, TZ >21 sec)
-invasive spine treatment including cortocoid injection up to 6 weeks ago or sheduled for the following 8 weeks
-hemophilia
-acute hernial disc
-congenital spine disorders
-known pregnancy or lactation
-therapy by opioid-analgetics
-insulin-dependent diabetes type 1
-systemic medication by corticoids or immunisuppressives
-acute psychotic disorders
-serious comorbidity

Addresses

- **Primary Sponsor**

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Sources of Monetary or Material Support

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

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- **Private sponsorship (foundations, study societies, etc.)**

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Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2015/12/14**

Trial Publications, Results and other documents

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

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