## Trial Description

<table>
<thead>
<tr>
<th><strong>Title</strong></th>
<th>Hypericum perforatum to improve post-operative pain outcome after monosegmental spinal microdiscectomy</th>
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<tbody>
<tr>
<td><strong>Trial Acronym</strong></td>
<td>HyPOS</td>
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<td><strong>URL of the trial</strong></td>
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### Brief Summary in Lay Language

Spinal disk herniation is one of the most common degenerative diseases of the spine. Many patients undergoing surgery suffer from neural pain known as "memory pain". As seen from the perspective of homeopathy, this pain can be treated using potentised St. John's Wort (Hypericum perforatum).

The present study investigates whether the additional application of Hypericum perforatum C200 leads to a pain reduction and a decrease of pain medication compared with placebo. The period of investigation is 5 days after surgery.

For the study, 100 patients of either sex between 18 and 85 years undergoing spinal disk operation are randomly allocated to Hypericum perforatum or placebo. Allocation is blinded, meaning that the surgeon does not know which treatment (Hypericum perforatum or placebo) is applied.

### Brief Summary in Scientific Language

The incidence of lumbar spinal stenoses increases dramatically due to the ageing population. In patients undergoing monosegmental spinal surgery, neural pain known as "memory pain" is observed. Experimental studies were able to show that the application of potentized Hypericum perforatum resulted in an improved regeneration and reconstitution of neural structures. Moreover, reduction of pain after application of Hypericum perforatum was observed in studies, i.e., in neuropathic pain, after knee ligament reconstruction or after tooth extraction. This study aimed to investigate whether adjuvant application of Hypericum Perforatum C200 leads to a decrease of post-operative pain and a decrease of pain medication compared to placebo.

The study is designed as a monocentric double-blind, randomized placebo-controlled trial. Study participants of either sex between 18 and 85 years are recruited from in-patients undergoing elective monosegmental spinal stenosis surgery. After surgery, patients are randomly selected into homeopathic treatment plus usual pain management vs. usual pain management with placebo.

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

[---]*
Do you plan to share individual participant data with other researchers?
[---]*

Description IPD sharing plan
[---]*

Organizational Data

- DRKS-ID: DRKS00007913
- Date of Registration in DRKS: 2015/03/25
- 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.: 49/2013, Ethik-Kommission der Universität Witten/Herdecke

Secondary IDs

- EudraCT-No. (for studies acc. to Drug Law): 2013-001383-31

Health condition or Problem studied

- Free text: Post operative pain after monosegmental spinal microdiscectomy
- ICD10: M51.1 - Lumbar and other intervertebral disc disorders with radiculopathy

Interventions/Observational Groups

- Arm 1: Patients of either sex between 18 and 85 years undergoing spinal microdiscectomy treated 3 - 5 days after surgery with conventional pain management and Hypericum perforatum C200
- Arm 2: Patients of either sex between 18 and 85 years undergoing spinal microdiscectomy treated 3 - 5 days after surgery with conventional pain management and placebo

Characteristics

- Study Type: Interventional
- Study Type Non-Interventional: [---]*
Study Type: Interventional
Study Type Non-Interventional: [---]*
- Allocation: Randomized controlled trial
- Blinding: [---]*
- Who is blinded: patient/subject, investigator/therapist, caregiver
- Control: Placebo
- Purpose: Treatment
- Assignment: Parallel
- Phase: IV
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): No

**Primary Outcome**

Pain reduction after 3rd postoperative day on 100mm VAS

**Secondary Outcome**

- Reduction of inpatient postoperative analgesic / antiphlogistic medication needs
- Pain reduction at 5 postoperative day
- Changes in sensory and affective pain perception (SES)

**Countries of recruitment**

- DE Germany

**Locations of Recruitment**

- Medical Center Gemeinschafts Krankenhaus Herdecke, Herdecke

**Recruitment**

- Planned/Actual: Actual
- (Anticipated or Actual) Date of First Enrollment: 2015/11/23
- Target Sample Size: 100
- Monocenter/Multicenter trial: Monocenter trial
- National/International: National

**Inclusion Criteria**
Gender: Both, male and female

Minimum Age: 18 Years

Maximum Age: 85 Years

Additional Inclusion Criteria

- Clinical indication for described spinal monosegmental Microdiscectomy
- Age between 18-85 years
- Existence of written informed consent
- full contractual capability

Exclusion criteria

- exclusion criteria for a neurosurgical procedure
- pre existing somatoform pain disorder
- continuous early retirement process due to back problems
- other chronic pain conditions than herniated disc
- pregnancy or lactation
- limited communication skills
- intake of sedativa
- intake of other homeopathic medicines
- severity comorbidity
- acute psychotic disorders
- participation in another clinical trial or termination of the participation of those less than 6 months
- existing placement in an institution by governmental or judicial authorities

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

Status

- Recruitment Status: Recruiting complete, follow-up complete
- Study Closing (LPLV): 2018/08/15

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.