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

Trial Description

Title

Effectivness of vagnial osteopathic treatment in women with acute low back pain

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

Many pregnant women suffer from back pain, caused by increased pressure to anatomical structures within the lesser pelvis. Different hands-on treatments like massage, physiotherapy and osteopathy can improve pain and other disorders. Intravaginal treatment can influence specific structures within the lesser pelvic. We investigate if osteopathic treatment additional intravaginal treatment has a larger effect than osteopathic treatment without intravaginal treatment.

Brief Summary in Scientific Language

In a randomized controlled trial the effects of osteopathic treatement with additional intravaginal treatement in pregnant women with acut low back pain is compared with osteopathic treatment allone. There is evidence for the effectiviness of manual therapy and osteopathic treatment for pregnant women with low back pain. Increaded pressure on specific anatomical structurs is seen as one reason in the pathogenesis of lumbar back pain in pregnant women. Intravaginal treatment might affect the plexus hypogastricus and might so induce lager benefit for the patients. Fourthy pregnant women between 30. - 36. week of pregnancy with acute low back pain will be randomized into two groups. All patients will be treated three times in a period of two weeks. Before and after each treatment, self-assessed pain levels using a visual analoge scale and the self-perceived functionality for pregnant women assessed by the Pregnancy-Mobiltiy-Index (PMD) will be examined. Statistical analysis will be performed using ANOVA with repeated measures.

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

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00010416**
- Date of Registration in DRKS: **2016/04/25**
- 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.: **012-32 , Ethikkommission des Osteopathic Research Institute**
  Mexikoring 19
  22297 Hamburg

Secondary IDs

Health condition or Problem studied

- ICD10: **M54.5 - Low back pain**
- Free text: **Back pain in pregnant women**

Interventions/Observational Groups

- Arm 1: **Osteopathic treatement, three times within two weeks a 45 min.**
- Arm 2: **Osteopathic treatment + intravaginal treatment, , three times within two weeks a 45 min**

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**

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

Self-reported pain by visual analog scale (VAS), before and after each treatment

Secondary Outcome

Self-reporte functionality by Oswestry-Low-Back-Pain Disability Index (ODI), before and after each treatment

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Doctor's Practice **Breitbrun**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2012/07/02**
- Target Sample Size: **46**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Female**
- Minimum Age: **18 Years**
- Maximum Age: **40 Years**

Additional Inclusion Criteria

30. - 36. week of pregnancy, pain in lumbar or pelvic region < 6Wochen

Exclusion criteria

multiple pregnancy, pregnancy risks (preterm labor, placenta praevia, vaginal bleeding, preeclampsia, eclampsia, HELLP syndrom), previous surgery of cervix and/or uterus, neurological disordes, psychaiatric disorders

Addresses

- **Primary Sponsor**

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  Germany

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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): **2013/02/03**

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.*