



Trial Description

Title

**The role of learning, stress and underlying brain circuits involving prefrontal-
limbic interactions in the development of chronic back pain**

Trial Acronym

LSCBP

URL of the trial

http://-

Brief Summary in Lay Language

Previous research leads to the assumption that emotional learning may play a major role in the development of chronic pain. However whether these learning processes really predict persistent pain is still not very well known and the role of stress in these processes is also not clear. This will be the target of the present study investigating patients with subacute and chronic back pain and healthy controls. Besides psychosocial factors, activation in specific brain regions will also be assessed.

Brief Summary in Scientific Language

Previous research leads to the assumption that emotional learning may play a major role in the development of chronic pain. While a number of studies have shown that psychosocial factors predict persistent pain, little is known how these relate to altered learning processes. Moreover, the changes in brain structure and function associated with learning mechanisms have not been examined in a longitudinal manner. Moreover, learning processes may interact with the experience of stress, which can alter pain processing and pain-related brain circuits.

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

[---]*

Description IPD sharing plan

[---]*

Organizational Data

■ DRKS-ID: **DRKS00008835**

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Date of Registration in DRKS: **2015/06/29**

- 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.: **2014-548N-MA , Medizinische Ethik-Kommission II
Medizinische Fakultät Mannheim der Universität Heidelberg**

Secondary IDs

Health condition or Problem studied

- Free text: **chronic back pain**
- ICD10: **M54 - Dorsalgia**

Interventions/Observational Groups

- Arm 1: **Observational study: Patients (investigation once, partly twice) - patients with chronic back pain perform different tasks (conditioning) at two measurement time points, depending on specific values regarding back pain (worsening in comparison to measurement time point 1)**
- Arm 2: **Observational study: healthy controls perform different tasks (conditioning) at one measurement time point**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Other**
- Allocation: **Non-randomized controlled trial**
- Blinding: [---]*
- Who is blinded: [---]*
- Control: **Other**
- Purpose: **Other**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Study Type: **Non-interventional**

Study Type Non-Interventional: **Other**

Allocation: **Non-randomized controlled trial**

Blinding: [---]*

Who is blinded: [---]*

Control: **Other**

Purpose: **Other**

Assignment: **Parallel**

Phase: **N/A**

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

Primary Outcome

Questionnaires on pain (West Haven-Yale Multidimensional Pain Inventory), anxiety (State-Trait-Anxiety Inventory) and depression (Beck Depression Scale) and tasks (conditioning) will be obtained for each participant at each measurement time point (measurement time points: 01.07.2015 - 30.06.2019)

Secondary Outcome

Persons, in whom back pain gets worse, will be measured twice (1 year after the first measurement time point, 01.07.2016 - 30.06.2019) using the conditioning tasks

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Doctor's Practice **Mannheim**

Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2015/07/01**
- Target Sample Size: **160**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**



Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **60 Years**

Additional Inclusion Criteria

subacute back pain, healthy individuals as control sample

Exclusion criteria

chronic and current drug consume, neurological disorder, left handedness, pregnancy, metal in the body

Addresses

■ Primary Sponsor

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Sources of Monetary or Material Support

- **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

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Status

- Recruitment Status: **Recruiting ongoing**
- 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.