



Trial Description

Title

Transition from localized low back pain to chronic widespread pain in general practice: Identification of risk factors, preventive factors, and key elements for treatment.

Trial Acronym

[---]*

URL of the trial

<http://www.login-verbund.de/index.php?id=15>

Brief Summary in Lay Language

Long running low back pain can widespread around the whole body. The name is chronic widespread pain. At the moment, informations about frequency of chonic widespread pain in primary setting does not exist. That question will be answered by this study. Although the study will find prognostic factors protecting chronic widespread pain and how influencing them.

Brief Summary in Scientific Language

The aim of the study is to identify predictors of pain generalization in consulters for low back pain in general practice and to identify individual resources for the prevention of the transition from chronic localized LBP to chronic widespread pain (CWP). These results provide the psychological background information on CWP patients which can be used for an intervention addressing resources and risk factors of this patient group.

Organizational Data

- DRKS-ID: **DRKS00003123**
- Date of Registration in DRKS: **2011/06/28**
- 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.: **88/10** , **Ethik-Kommission des Fachbereichs Medizin der Philipps-Universität Marburg**

Secondary IDs



Health condition or Problem studied

- Free text: **chronic widespread pain,**
- ICD10: **M54.8 - Other dorsalgia**

Interventions/Observational Groups

- Arm 1: **Patients with chronic local low back pain during point of time T0 will include in a cohort study and observed with regard of pain localisation.**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **Single arm study**
- Blinding: **Open (masking not used)**
- Who is blinded: **[---]***
- Control: **Uncontrolled/Single arm**
- Purpose: **Prognosis**
- Assignment: **Single (group)**
- Phase: **[---]***
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

Primary endpoint: Propability getting a chronic widespread pain for patients with chronic local low back pain during one year. Measuring: questionnaires, every 3 months. The questionnaire consists of a body pain drawing (Pfau et al. 2009*) where patients drawing in their pain. The analysis will done by the definition of Wolfe et al 1999*.

*** Pfau Doreen B. et al. Somatosensory profiles in subgroups of patients with myogenic temporomandibular disorders and fibromyalgia syndrome. Pain. 147 (2009) 72-83.**

*** Wolfe et al. The american college of rheumatology 1999 criteria for the classification of fibromyalgie. Arthritis and Rheumatism, Vol. 33, No. 2 (February 1990).**

Secondary Outcome

prevalence of local chronic low back pain and prevalence of chronic widespread pain in primary care setting. Measurement: questionnaire, to point of time To.



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Countries of recruitment

- DE **Germany**

Locations of Recruitment

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2011/06/01**
- Target Sample Size: **1000**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

all patients consulting their family doctor because of chronic* low back pain during a time of 4 month.

*** chronic = pain during most days in the last three month.**

**** low back pain = Pain in the back area under the costal arch an over the bottum fold.+/- radiation.**

Exclusion criteria

- **lack of fluency**
- **age < 18 years**
- **pregnancy**

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.