

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

## Trial Description

### Title

**Examination of peripheral nerve system using high resolution ultrasound in polyneuropathy**

### Trial Acronym

**NeuroPNP-US**

### URL of the trial

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### Brief Summary in Lay Language

**Polyneuropathies (PNP) are generalized diseases of the peripheral nervous system consisting out of sensory disabilities, muscular weakness, autonomic deregulation and pain. These symptoms are caused by damage of large or small nerve fibers. Etiology is different and often unknown, among these inflammation, toxic or metabolic disorders and cancer. Also hereditary forms of PNP are frequent. In most cases generalized damage of PNS is caused by alcohol and diabetes mellitus in industrial countries and bacterial infections in developing countries. Peripheral damage can affect axons (axonal PNP) of the nerve or myelin (demyelinating PNP) or both. The current gold standard for diagnosis of polyneuropathies consists of a careful neurological examination together with nerve conduction studies and sometimes electromyographic (EMG) measurements. In recent years it was shown that ultrasound of peripheral nerve system could point out interesting pathologic phenomenon in peripheral nerve system. In this study we thus wanted to clarify hypothesis of ultrasound revealing differences between both entities and thus facilitating diagnosis and differentiation of PNP. We plan electrophysiological and sonographical examinations of patients with demyelinating, axonal or mixed neuropathy and want to compare them to a healthy control group.**

### Brief Summary in Scientific Language

**Polyneuropathies (PNP) are generalized diseases of the peripheral nervous system consisting out of sensory disabilities, muscular weakness, autonomic deregulation and pain. These symptoms are caused by damage of large or small nerve fibers. Etiology is different and often unknown, among these inflammation, toxic or metabolic disorders and cancer. Also hereditary forms of PNP are frequent. In most cases generalized damage of PNS is caused by alcohol and diabetes mellitus in industrial countries and bacterial infections in developing countries. Peripheral damage can affect axons (axonal PNP) of the nerve or myelin (demyelinating PNP) or both. The distribution of damage can be distinguished in symmetric distal PNP, which means affection of mainly both hands and feet, mononeuropathy multiplex, which means affection of single large nerves and mixtures of both entities. The current gold standard for diagnosis of polyneuropathies consists of a careful neurological examination together with nerve conduction studies and sometimes**

**electromyographic (EMG) measurements. Clinical signs are reduction or loss of different sensory functions, muscular weakness or atrophy or autonomic disorders such as erectile dysfunction, heart rhythm deregulation or cardio-vascular problems. Typical electroneurographic signs of axonal PNP - briefly spoken - are reductions of the amplitude of compound muscle action potentials (CMAP) as well as sensory nerve action potentials (SNAP) and only slight reduction of conduction velocity (<20%). Typical signs of demyelinating PNP are reduction of motor and sensory nerve conduction velocity (>20%), increased temporal dispersion of motor nerve response and increasement of distal motor latency (>20%) as well as prolongation of F-wave-latency. A reduction of amplitude of motor and sensory nerve (CMAP and SNAP) is possible in demyelinating PNP and reduction of CV is possible in axonal PNP (caused by degeneration of fast large fibers or distal conduction block) and thus must be interpreted carefully. A big part of PNP is a combined axonal and demyelinating form and a distinction between axonal and demyelinating PNP is often not clear. Nevertheless this distinction of both is the main goal in examination PNP due to different etiologies and thus therapies. The accurate method to classify PNP is the nerve biopsy which is invasive and only few centers can interpret them.**

**In the last years ultrasound of the peripheral nerve system got into focus of interest in entrapment syndromes, nerve tumors and focal nerve lesions and its worth could be pointed out in several studies. Imaging of nerve system would also be of huge interest in systemic disorders of peripheral nerve system.**

**Several groups showed that ultrasound of peripheral nerve system could point out pathologic phenomenon in polyneuropathy as swollen cross-sectional area CSA in de- and remyelinated neuropathies seen as onion bulbs in histology. Patients with hereditary PNP suffer from diffuse nerve enlargement whereas patients with immune-mediated neuropathies suffer from multifocal nerve enlargement fitting to nerve conduction block. As mentioned before electrophysiological and clinical differentiation between axonal and demyelinating PNP is not as straightening. In this study we thus want to clarify hypothesis of ultrasound revealing differences between both entities and thus facilitating diagnosis and differentiation of PNP. We furthermore want to point out, whether dimension of nerval damage in ENG correlates with changes in ultrasound as described in one study.**

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

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**Description IPD sharing plan**

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## Organizational Data

- DRKS-ID: **DRKS00005253**
- Date of Registration in DRKS: **2013/10/15**
- 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.: **3663-01/13 , Ethikkommission der Friedrich-Schiller-Universität Jena an der Medizinischen Fakultät**

## Secondary IDs

## Health condition or Problem studied

- ICD10: **G60 - Hereditary and idiopathic neuropathy**
- Free text: **Polyneuropathy**

## Interventions/Observational Groups

- Arm 1: **Demyelinating neuropathy, ultrasound and electrophysiology of the nerves in one visitation**
- Arm 2: **Axonal Neuropathy, program arm 1**
- Arm 3: **Mixed Neuropathy, program arm 1**
- Arm 4: **Healthy controls, program arm 1**

## Characteristics

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

## Primary Outcome

**Ultrasound measurements of cross-sectional area (CSA) in different nerves and different locations will be done in one visitation together with electrophysiological gold standard. CSA of demyelinating, axonal and composed neuropathy will be compared to healthy controls**

## Secondary Outcome

## **Predictability in diagnosis different types of neuropathy (axonal, demyelinating and composed) according to CSA**

### **Countries of recruitment**

- **DE Germany**
- **CH Switzerland**

### **Locations of Recruitment**

- University Medical Center **Basel**
- University Medical Center **Jena**

### **Recruitment**

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2013/04/01**
- Target Sample Size: **90**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

### **Inclusion Criteria**

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **99 Years**

### **Additional Inclusion Criteria**

**Polyneuropathy**

### **Exclusion criteria**

**other neuromuscular disorders**

### **Addresses**

- **Primary Sponsor**  
**Universitätsspital Basel**  
**Mr. Dr. Alexander Grimm**

### **Primary Sponsor**

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### ■ **Contact for Scientific Queries**

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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 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.