PLEASE NOTE: This trial has been registered retrospectively.

Trial Description

Title

Mechanisms and predictors of pain resolution in complex regional pain syndrome (CRPS) and chronic postsurgical inguinal pain

Trial Acronym

ResolvePain CRPS CPIP

URL of the trial

[---]*

Brief Summary in Lay Language

This study examines chronic inguinal pain and the complex regional pain syndrome.

After an injury, the very painful complex regional pain syndrome (CRPS) can occur. This is a chronic pain syndrome that results in swelling, discoloration, temperature changes and severe functional limitations of the affected limb after injury. The affected patients can no longer use this limb in everyday life and the pain is unfortunately difficult to influence. Unfortunately, we do not know prognostically why in some patients the CRPS improves significantly to the point of freedom from symptoms and why not in others and would like to pursue exactly this question in our research project.

Chronic inguinal pain is one of the major complications after inguinal hernia surgery and can occur in up to 14% of all patients, which is why the study of this disease is of immense importance. Although a variety of risk factors for this complication have already been identified, it is still unclear why some patients improve pain significantly, right down to symptom-free, and why others do not. We would like to pursue this question in our research project.

For this purpose, patients are included in groin surgeries or with CRPS and then monitored for one year. In addition, diagnostic examinations such as MRI and biopsy are performed to find measurements that allow prognosis of chronic inguinal pain or CRPS.

Brief Summary in Scientific Language

In this diagnostic and observational study, molecular, clinical, or imaging predictors of healing are expected. Chronification CRPS and chronic postoperative inguinal pain can be identified.

Organizational Data
Secondary IDs

Health condition or Problem studied

- ICD10: M89.0 - Algoneurodystrophy
- ICD10: G57.8 - Other mononeuropathies of lower limb
- ICD10: G56.4 - Causalgia
- ICD10: R10.3 - Pain localized to other parts of lower abdomen

Interventions/Observational Groups

- Arm 1: CRPS type I or II, upper and lower extremity in a long-term observation with advanced diagnostics such as questionnaires, biomarkers in the blood and skin tissue as well as changes in dorsal root ganglia (MRI)
- Arm 2: Chronic inguinal pain after inguinal hernia repair in a long-term observation with advanced diagnostics such as questionnaires, sensory profiles, biomarkers in the blood and skin tissue as well as changes in dorsal root ganglia (MRI)
- Arm 3: healthy controls for advanced diagnostics such as questionnaires, diagnostics such as questionnaires, biomarkers in the blood and skin tissue as well as changes in dorsal root

Characteristics

- Study Type: Non-interventional
- Study Type Non-Interventional: Other
- Allocation: Other
- Blinding: [---]*
- Who is blinded: [---]*
- Control: Other
- Purpose: Prognosis
Study Type: Non-interventional
Study Type Non-Interventional: Other
Allocation: Other
Blinding: [---]*
Who is blinded: [---]*
Control: Other
Purpose: Prognosis

- Assignment: Other
- Phase: N/A
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): [---]*

**Primary Outcome**

Expression of a cell adhesion molecule in the skin

**Secondary Outcome**

Alterations in microRNAs, altered permeability in DRGs

**Countries of recruitment**

- DE Germany

**Locations of Recruitment**

- University Medical Center Klinik für Anäesthesiologie, Würzburg

**Recruitment**

- Planned/Actual: Actual
- (Anticipated or Actual) Date of First Enrollment: 2018/10/01
- Target Sample Size: 300
- Monocenter/Multicenter trial: Monocenter trial
- National/International: National
Gender: **Both, male and female**

- Minimum Age: **18 Years**
- Maximum Age: **85 Years**

### Additional Inclusion Criteria

**CRPS or chronic inguinal pain**

### Exclusion criteria

Lack of the ability to give informed consent; contraindications to the procedure for an MRI examination, such as the presence of metal foreign bodies, e.g. pacemakers, paramagnetic vascular clips, garnet splinters, metallic endoprosthesis; pregnancy; clausrophobia, contrast media intolerance, terminal renal insufficiency and acute renal failure, severe asthma.

### Addresses

**Primary Sponsor**

Universitätsklinikum Würzburg  
Josef-Schneider-Str.  
97080 Würzburg  
Germany  

Telephone: [--]*  
Fax: [--]*  
E-mail: [--]*  
URL: [www.klinik.uni-wuerzburg.de](http://www.klinik.uni-wuerzburg.de)

**Contact for Scientific Queries**

Klinik für Anästhesiologie  
Ms. Prof. Dr. Heike Rittner  
Oberdürrbacher Str. 6  
97080 Würzburg  
Germany  

Telephone: **49 931 201 30251**  
Fax: **49 931 201 30259**  
E-mail: rittner_h at ukw.de  
URL: [--]*

**Contact for Public Queries**

Klinik für Anästhesiologie Zentrum für Interdisziplinäre Schmerzmedizin  
Ms. Prof. Dr. Heike Rittner  
Josef-Schneider-Str. 6  
97080 Würzburg
Contact for Public Queries

Klinik für Anästhesiologie Zentrum für Interdisziplinäre Schmerzmedizin
Ms. Prof. Dr. Heike Rittner
Josef-Schneider-Str. 6
97080 Würzburg
Germany

Telephone: 49 931 201 30251
Fax: 49 931 201 30259
E-mail: rittner_h at ukw.de
URL: [---]*

Sources of Monetary or Material Support

- Institutional budget, no external funding (budget of sponsor/PI)

Universitätsklinikum Würzburg
Josef-Schneider-Str.
97080 Würzburg
Germany

Telephone: [---]*
Fax: [---]*
E-mail: [---]*
URL: www.klinik.uni-wuerzburg.de

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.