**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**

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**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.

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

Description IPD sharing plan
[---]*

Organizational Data

- DRKS-ID: DRKS00016790
- Date of Registration in DRKS: 2019/02/20
- 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.: 242/17-sc, Ethik-Kommission der Medizinischen Fakultät der Universität Würzburg

Secondary IDs

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

Health condition or Problem studied

- 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
- 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 Anästhesiologie, 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

Inclusion Criteria
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; claustrophobia, contrast media intolerance, terminal renal insufficiency and acute renal failure, severe asthma.

### Addresses

#### Primary Sponsor

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Sources of Monetary or Material Support

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

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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.

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