Trial Description

Title

Influence of scratching on skin profiles in chronic pruritus patients

Trial Acronym

Influence of scratching on skin profiles

URL of the trial

[---]*

Brief Summary in Lay Language

Chronic itch is a frequent symptom of many different conditions, but its underlying disease processes remain unclear. Scratching occurs in both acute and chronic forms of itch and leads to visible damage and changes to the skin, impairing the patients' quality of life. This study aims to investigate the influence of scratching on various disease mechanisms of itch.
120 patients with different itchy diseases (itch due to neurodermatitis, nerve compression and kidney malfunction), 90 healthy individuals and 30 patients reporting low itch will be included. A series of tests and examinations will be performed; these include skin testing with substances causing itch, stimulation of the skin with electricity, questionnaires and skin biopsies. Biopsies will be taken in itchy damaged skin, itchy normal skin and non-itchy normal skin.
The specific objectives of this study are to (1) to analyze the structure of skin nerves in different itchy conditions, (2) to identify what genes are important in different itchy conditions and (3) to identify relationships between the scratching-related changes to the skin, clinical properties of the itch and nerve fiber function. This study is part of a research consortium, working closely together to identify relevant aspects of chronic itch in order to develop new therapies.

Brief Summary in Scientific Language

Chronic pruritus (CP) is a highly prevalent symptom of many different diseases, but its underlying pathophysiological mechanisms remain unclear. Scratching is a hallmark of acute and chronic pruritus and frequently leads to visible damage and alterations of the skin and therefore to a high burden of suffering and an impairment of the patient's quality of life. This study aims to investigate the influence of scratching on the cellular and molecular mechanisms of pruritus.
120 patients with CP of different origin will be included (atopic dermatitis, brachioradial pruritus, notalgia paresthetica and uremic pruritus) as well as 120 controls (90 healthy controls and 30 patients reporting low pruritus intensities (NRS<3/10)). A series of experimental tests will be performed including focal electrical stimulation, stimulation with a chemical substance (cowhage), patient questionnaires, skin biopsies (for morphological characterization of nerve fibers, expression of specific pruritic markers, global gene expression profiles). In patients, biopsies will be taken in pruritic lichenified skin, pruritic non-lichenified

skin and healthy skin, whereas in healthy controls biopsies will be obtained from healthy skin and in low-pruritus controls biopsies will be taken from pruritic non-lichenified skin and healthy skin.
The specific objectives of this study are thus (1) to characterize cutaneous nerve fibers in CP of different origins, (2) to identify specific gene expression profiles in CP of different origins, and (3) to identify causal relationships between scratching-related changes and clinical and functional parameters.
This patient-oriented study is part of a research consortium, working closely together to identify clinically and therapeutically relevant mediators of chronic pruritus and related anatomical and functional neuronal changes in patients.

Organizational Data

- DRKS-ID: **DRKS00014745**
- Date of Registration in DRKS: **2018/05/28**
- 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.: **2017-562-f-S , Ethik-Kommission der Ärztekammer Westfalen-Lippe und der med. Fakultät der Westfälischen Wilhelms-Universität Münster**

Secondary IDs

- Sponsor-ID: **SST-Pr-32-2017**

Health condition or Problem studied

- ICD10: **L20 - Atopic dermatitis**
- ICD10: **L29.8 - Other pruritus**

Interventions/Observational Groups

- Arm 1: <style fontName='DejaVu Sans' isBold='true'>120 patients with CP (chronic pruritus) of different origin will be included (atopic dermatitis, brachioradial pruritus, notalgia paresthetica and uremic pruritus). A series of experimental tests will be performed including focal electrical stimulation, stimulation with a chemical substance (cowhage), patient questionnaires, skin biopsies (for morphological characterization of nerve fibers, expression of specific pruritic markers, global gene expression profiles). In patients, biopsies will be taken in pruritic lichenified skin, pruritic non-lichenified skin and healthy skin, whereas in healthy controls biopsies will be obtained from healthy skin and in low-pruritus controls biopsies will be taken from pruritic non-lichenified skin and healthy skin.
  The above described experimental procedures will be also performed in 120 controls (90 healthy controls and 30 patients reporting low pruritus intensities (NRS<3/10)).</style>

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Other**
- Allocation: **Single arm study**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Uncontrolled/Single arm**
- Purpose: **Basic research/physiological study**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Morphological parameters: epidermal and dermal nerve fiber density, caliber deviations, branching, characterization of nerve fibers (myelin, neuropeptides, non-peptidergic markers, receptor expression)
Functional parameters: pruritus intensity evoked by electrical stimulation, pruritus/pain intensity evoked by stimulation with cowhage
Immunostaining: expression of pruritic mediators
Gene expression: cutaneous global gene expression profiles, differential expression profiles
Patient questionnaires: NeuroDerm questionnaire, 5PLQ, SF12, Beck´s Depression Inventory (BDI), Trait anxiety inventory (STAI-T), Self-Administered Comorbidity Questionnaire (SCQ), Brief Pain Inventory (BPI), Pain Catastrophizing Scale, Neuropathic pain symptom inventory (NPSI).
Assessments will be performed once for each study pariticipant.

Secondary Outcome

not applicable

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Klinik für Hautkrankheiten und Kompetenzzentrum chronischer Pruritus (KCP), Universitätsklinikum Münster Von-Esmarch-Str. 58 48149 Münster, Münster**

Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2018/06/01**
- Target Sample Size: **240**
- 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

Patients with chronic pruritus (due to atopic dermatitis, brachioradial pruritus, notalgia paresthetica or uremic pruritus); minimum age 18 years; skin type I-IV (Fitzpatrick classification); caucasians;

Exclusion criteria

Patients who cannot complete the questionnaires due to physical or psychiatric diseases or an insufficient understanding of the German language. Patients taking antipruritic drugs. Patients with an infection at the potential biopsy area.

Addresses

- **Primary Sponsor**

  Klinik für Hautkrankheiten und Kompetenzzentrum chronischer Pruritus (KCP), Universitätsklinikum Münster
  Ms. Univ.-Prof. Dr. med. Dr. h.c. Sonja Ständer
  Von-Esmarch-Str. 58
  48149 Münster
  Germany

  Telephone: **[---]***
  Fax: **[---]***
  E-mail: **juckreizambulanz at ukmuenster.de**
  URL: **http://klinikum.uni-muenster.de/index.php?id=977**
- **Contact for Scientific Queries**

  Klinik für Hautkrankheiten und Kompetenzzentrum chronischer Pruritus (KCP)Universitätsklinikum Münster

Contact for Scientific Queries

Klinik für Hautkrankheiten und Kompetenzzentrum chronischer Pruritus (KCP)Universitätsklinikum Münster
Mr. Dr. med. Konstantin Agelopoulos
Von-Esmarch-Str. 58
48149 Münster
Germany

Telephone: **00492518358950**
Fax: **[---]***
E-mail: **agelopoulos at uni-muenster.de**
URL: **https://www.ukm.de/index.php?id=977**

- **Contact for Public Queries**

Klinik für Hautkrankheiten und Kompetenzzentrum chronischer Pruritus (KCP)Universitätsklinikum Münster
Mr. Dr. med. Konstantin Agelopoulos
Von-Esmarch-Str. 58
48149 Münster
Germany

Telephone: **+49 (0) 251/83-58950**
Fax: **[---]***
E-mail: **agelopoulos at uni-muenster.-de**
URL: **https://www.ukm.de/index.php?id=977**

Sources of Monetary or Material Support

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

Klinik für Hautkrankheiten und Kompetenzzentrum chronischer Pruritus (KCP), Universitätsklinikum Münster
Von-Esmarch-Str. 58
48149 Münser
Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

Status

- Recruitment Status: **Recruiting planned**
- 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.*