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

Trial Description

Title

Painful Itch in Hand Eczemas: Frequency and Characteristics in a Consecutive, Representative Collective of Dermatological Patients

Trial Acronym

SST-Pr-20-2011

URL of the trial

[---]*

Brief Summary in Lay Language

The hand is equally sensitive to pruritus and pain, whereas the face is more sensitive to pain, and the distal extremities are more sensitive to pruritus. No survey has been made on the frequency and quality of pruritus and pain in the hand in patients with chronic pruritus (CP). The goal of the present questionnaire-based study is to describe these qualities in a consecutive cohort of patients with CP. Within the context of routine care, patients were given a questionnaire that specifically addresses symptoms in the hand, including quality, intensity and skin condition. Thereafter, patients were given antipruritic treatment according to current guidelines and independent of the questionnaire data. At the return visit, patients were once again given the questionnaire to complete. In addition, at every visit, skin hydration was measured by corneometry and D-squames.

Brief Summary in Scientific Language

Many patients with CP (CP: more than six weeks' duration) report experiencing sensory sensations in their hands; however, neither the resulting impaired hand functionality not the severity of these sensations was investigated so far. Furthermore, no precise data have been collected on itch qualities in CP. Presumably, pain or overlapping qualities of itch is higher than expected, since skin lesions resulting from scratching lead to pain. Correspondingly, there are also no data on differential reduction in itch and pain qualities achieved by means of anti-pruritus therapy. This questionnaire-based study should help gather data on these issues. Within the context of routine care, patients with CP of all origins receive a questionnaire specially developed for the hand (module of the NeuroDerm questionnaire) for assessing the skin condition. On the assumption that about 50% of patients present with atopic diathesis, skin hydration is measured with a corneometer and D-squames in order to correlate changes in patient reports with the barrier function.

Organizational Data

- DRKS-ID: **DRKS00005238**
- Date of Registration in DRKS: **2013/08/19**
- 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.: **2007-413-f-S, Amendment 6 , Ethik-Kommission der Ärztekammer Westfalen-Lippe und der med. Fakultät der Westfälischen Wilhelms-Universität Münster**

Secondary IDs

Health condition or Problem studied

- ICD10: **L29.9 - Pruritus, unspecified**

Interventions/Observational Groups

- Arm 1: **Each patient with CP visiting the Competence Center for Chronic Pruritus receives, in addition to a set of routine questionnaires, a separate questionnaire addressing hand pruritus. As a rule, the question whether pruritus is present in the hand should be answered first (Question 1). If yes, then further questions are asked regarding the topography, duration, presence of dermatoses, intensity, quality, emotional assessment, limitations of activities of daily living and limitations on the use of hand in relation to the symptoms. In addition, data on routine parameters are acquired and assessed: case history, clinical examination, pruritus intensity scales (for the whole body), Erlangen Atopy Score, NeuroDerm Questionnaire, DLQI (Dermatological Life Quality Index; Range 0-30) and HADS (Hospitality Anxiety and Depression Scale; Range 0-21, separately for anxiety and (A) and depression (D)). Skin hydration is digitally measured using Tesa tape to strip scales from the superficial skin layer. For this purpose, a round, special foil 1x1cm in size is taped on the patient’s skin. A few scales loosened by the desquamation process remain attached to the foil after it is stripped from the skin. The process is comparable to taping a piece of Tesa film on to the skin and then stripping it, which does not injure or irritate the skin. The foil is then pasted on to the skin analysis card. With the help of a microscope camera, the foil is photographed and then subjected to computer analysis.**

Characteristics

- Study Type: **Non-interventional**
-

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Study Type Non-Interventional: **Epidemiological study**

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

Primary Outcome

Assessment of frequency of pruritus at the hand (module hand of the NeuroDerm questionnaire) of patients with chronic pruritus

Secondary Outcome

Describtion of quality of pruritus at the hand (module hand of the NeuroDerm questionnaire) in patients with chronic pruritus
Correlation of skin hydration (corneometry) with presence of pruritus at the hand

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Kompetenzzentrum Chronischer Pruritus (KCP), Klinik für Hautkrankheiten, Münster**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2012/03/05**
- Target Sample Size: **1500**
- 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 (> 6 weeks of duration)

Exclusion criteria

disorders preventing participation in the investigation

Addresses

- **Primary Sponsor**

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  Universitätsklinikum Münster
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  Fax: **[---]***
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  URL: **[---]***

- **Contact for Scientific Queries**

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URL: **[---]***

Sources of Monetary or Material Support

- **Commercial (pharmaceutical industry, medical engineering industry, etc.)**

  GlaxoSmithKline GmbH & Co. KGGeschäftsbereich Stiefel Dermatologie
  Vormals: Basilea Pharmaceutica Deutschland GmbH
  Prinzregentenplatz 9
  81675 München
  Germany

  Telephone: **[---]***
  Fax: **[---]***
  E-mail: **[---]***
  URL: **[---]***
- **Institutional budget, no external funding (budget of sponsor/PI)**

  Universitätsklinikm MünsterKompetenzzentrum Chronischer Pruritus und Klinik für Hautkrankheiten
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  URL: **[---]***

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2013/02/05**

Trial Publications, Results and other documents

- Abstract **Abstract**

** 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.*