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

Trial Description

Title

Minimal clinical important difference (MCID) on pruritus scales

Trial Acronym

PruMCID

URL of the trial

[---]*

Brief Summary in Lay Language

Many patients suffer from a long-standing itch (Pruritus). Currently, there are no objective criteria to measure the severity or quality of the symptom. Hence, subjective scales are used for assessing the course of this condition. The clinical usefulness of these scales is not yet clear.
A total of 250 patients will be requested to answer questions on the severity of their itch, both in writing and orally, using various scales. Patients will be asked these questions at three different time points (day 1, after 5-14 days and after 4-6 weeks). On the basis of the data obtained, we can determine the difference between two values on a given scale which is required for achieving a clinically significant subjective effect (improvement or deterioration) in the patient. This should help assess the course of symptoms in a more precise manner.

Brief Summary in Scientific Language

Data acquisition on itch is currently carried out in a standardised fashion using intensity scales (visual analogous scale - VAS; numerical rating scale - NRS and verbal rating scale - VRS). The scales enable reliable and valid measurement of symptoms. It is unclear which reduction on a given scale measures a clinically perceptible effect in the course of pruritus. Till now, there has been no study on the so-called minimal clinically important difference (MCID) in the scales. It is important to determine MCID for assessment of the course of the symptoms in the clinical routine and for statistical calculations and end-point definitions in clinical studies.

Organizational Data

- DRKS-ID: **DRKS00005732**
- Date of Registration in DRKS: **2014/03/10**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***

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Date of Registration in DRKS: **2014/03/10**
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- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **2007-413-f-S , 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: **Patients should fill at three time points (day 1, day 5-14, 4-6 weeks) a questionnaire with questions about the course of symptoms. This relates to the general change of pruritus, the direction (better / worse) and Quantity of change and the Pruritusintensität (VAS-visual analog scale, NRS-numeric rating scale, VRS-verbal rating scale), quality of life and anxiety and depression.**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational 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

Determining the MCID (minimal clinical important difference) on the VAS (visual analogue scale) by questionnaire at the time of 5-14 days (time point 2) or 4-6 weeks (time 3) compared to day 0 (time 1)

Secondary Outcome

Determining the MCID (minimal clinical important difference) on the NRS (Numerical Rating Scale) and VRS (Verbal Rating Scale) by questionnaire at the time of 5-14 days (time point 2) or 4-6 weeks (time 3) compared to day 0 (time 1)

Countries of recruitment

- DE **Germany**

Locations of Recruitment

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

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2011/08/22**
- Target Sample Size: **250**
- 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 itch treated in outpatient and inpatient settings

Exclusion criteria

Patients who cannot fill in the questionnaire (e.g., because of current psychosomatic or psychiatric disease)

Addresses

■ **Primary Sponsor**

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Fax: **[---]***
E-mail: **[---]***
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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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Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2012/06/05**

Trial Publications, Results and other documents

- Abstract **PDF**

** 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.*