Trial Description

Title

Characterization of the role of blood circulation and neovascularization in acute and chronic pruritus

Trial Acronym

iETOP

URL of the trial

[---]*

Brief Summary in Lay Language

The aim of this study is the identification and characterization of the importance of increased blood circulation and neovascularization in patients with chronic pruritus and in experimental models of acute induced pruritus in healthy volunteers.

Brief Summary in Scientific Language

The present trial has the aim to verify the following hypotheses:
1. Various models of experimental induction of pruritus on healthy lead to increased capillary blood flow.
2. Reduction of blood flow at the site of itching reduce the severity of pruritus in healthy volunteers
3. Patients with prurigo (chronic pruritus with secondary scratch lesions) have an increased vascularity at the site of the itching
4. Local reduction of blood flow and possibly of neovascularization reduce severity of pruritus in patients suffering from prurigo

Organizational Data

- DRKS-ID: **DRKS00008764**
- Date of Registration in DRKS: **2015/07/10**
- 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.: **EA4/103/14 , Ethik-Kommission der Charité - Universitätsmedizin Berlin-**

Secondary IDs

- Universal Trial Number (UTN): **U1111-1171-1359**

Health condition or Problem studied

- Free text: **chronic pruritus in patients suffering from prurigo**
- Free text: **Acute pruritus in itching models**
- ICD10: **L28.2 - Other prurigo**
- Free text: **Healthy volunteers**

Interventions/Observational Groups

- Arm 1: **The study has two different parts. In the first part, the relationship between blood flow and acute itching is determinate in healthy volunteers. We will induce acute pruritus in healthy volunteers by using different models, including skin prick test on the forearm.**
  Blood flow using laser speckle method, pruritus using NRS and diameter of wheal and/or erythema will be determinate in these provoked areas.
  The effect of locally applied brimonidine and propranolol will be assess.
- Arm 2: **In a second part of the study, the relationship between blood flow and chronic pruritus will be evaluate in patients suffering from prurigo.**
  Pruritus using NRS and blood flow using laser speckle method will be assess in affected skin areas. The short-term effect of topical applicate brimonidine and propranolol on the above-mentioned factors will be determinate. We are looking for the medium- and longer-term effects by topical application of Propranolol in over four weeks. We will determinate blood flow by laser speckle method, the pruritus by NRS and we do a score for severity of erythema, crusts, scratching and infiltration. A three-dimensional image of the skin surface before and after application will be done in order to detect possible changes. In addition to an optional new innovative skin micro biopsy will be perform.
- Arm 3: **For evaluation of the medium- and longer-term effects the Patient will receive a vehicel for a index leasion over four weeks. We will determinate blood flow by laser speckle method, the pruritus by NRS and we do a score for severity of erythema, crusts, scratching and infiltration. A three-dimensional image of the skin surface before and after application will be done in order to detect possible changes. In addition to an optional new innovative skin micro biopsy will be perform.**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Non-randomized controlled trial**
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Blinding: **[---]***

- Who is blinded: **patient/subject**
- Control: **Placebo**
- Purpose: **Basic research/physiological study**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **Yes**

Primary Outcome

Reduction of blood circulation unter propranolol using Laser- Speckle- method (before and after application over a period of four weeks)

Secondary Outcome

-Reduction of pruritus under propranolol using NRS (before and after application over a period of four weeks)
-Reduction of volumetric measurements under propranolol using PRIMOS (before and after application over a period of four weeks)
-Reduction of patient global assessment under propranolol (before and after application over a period of four weeks)
-Reduction of severity score under propranolol (before and after application over a period of four weeks)

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Charité - universitätsmedizin Berlin, Berlin**

Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2015/07/31**
- Target Sample Size: **40**

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- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **90 Years**

Additional Inclusion Criteria

Inclusion criteria healthy subjects:
The volunteers must be over eighteen, and be able to communicate with the investigator. They must be able to understand the contents of the study and they need to consent to participate in the study. Only male subjects.

Inclusion criteria patients:
1. Signed informed consent
2. Prurigo patients with chronic pruritus (> 6 months) and a severity of prurigo using VAS ≥ 6/10
3. The patient willing to only use the mentioned products and no other own externa. As rescue medication in severe itching, patients receive a care cream DAC base cream that can be applied as often as desired.
4. Of full age
5. Both male and female patients

Exclusion criteria

Exclusion criteria subjects:
Known history of hypersensitivity to any of the substances to be applied.
Regular or current intake of medications against itch such as antihistamines, topical or systemic steroids, immunosuppressants or gabapentin.
Participation in a clinical trial in the last 30 days.

Exclusion criteria patients:
1. Therapeutic UV radiation during the last 6 weeks before the start of the investigation or during the investigation
2. Topical antihistamines, steroids or mast cell stabilizers in the last 3 weeks prior to the study or during the study
3. Systemic medications such antihistamnika, antidepressants, antipsychotics, corticosteroids are permitted if:
a) the medication were taken since at least the last 4 weeks prior to the study and
b) there has been no changes regarding the use or dosage during the study
4. A history of hypersensitivity to any of the substances to be applied
5. Diseases that does not allow to include patients in the study, assessed by the investigator

6. Pregnant or lactating women or planned pregnancies during the study
7. Participation in another study in the last 30 days.

Addresses

■ **Primary Sponsor**

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Sources of Monetary or Material Support

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

Charité Campus Charité Mitte

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

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E-mail: **[---]***
URL: **www.charite.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.*