Trial Description

Title

Qutenza TM in notalgia paresthtetica: pharmacoeconomic evaluation and patient acceptance with focus on intraepidermal C-fiber eradication

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

The aim of the study is to evaluate pharmacoeconomics and acceptance of Qutenza patch for patients suffering from notalgia paraesthetica or brachioradial pruritus. It should be evaluated if application decreases follow up costs of treatments and correlates with intraepidermal nerve fiber density.

Brief Summary in Scientific Language

The aim of the study is to document therapy with neuropathic pain syndromes such as Qutenza in a series of patients suffering from notalgia paraesthetica or brachioradial pruritus with special focus on
1. the economic evaluation of therapies incl. treatment regimens under consideration of symptom changes and
2. the patient acceptance of Qutenza with regard to clinical symptoms (Pruritus, Burning, Pain e.g.), quality of life, fear and depression.
As objectiv marker of treatment effectiveness intraepidermal nerv growth is used. Data will be collected 6 and 3 months retrospectively and prospectivels. Nerve growth will be analyzed at time of application as well as 3, 12, and 24 weeks after.

Organizational Data

- DRKS-ID: **DRKS00005189**
- Date of Registration in DRKS: **2013/09/10**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **no**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **2011-462-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: **M79.29 - [generalization M79.2: Neuralgia and neuritis, unspecified]**

Interventions/Observational Groups

- Arm 1: **Patients with Notalgia paraesthetica or brachioradial pruritus fill out several questionaires concerning clinical symptoms, quality of life and medical treatment regimens/costs and are treated with Qutenza if indicated. Within routine a skin biospy is taken.**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **Single arm study**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Uncontrolled/Single arm**
- Purpose: **Health economics**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **No**

Primary Outcome

Pharmacoeconomic and clinical evaluation of prescription patterns, symptoms, quality of life and nerve growth 3/6 months retrospectively and 3/6 months prospectively.

Secondary Outcome

none

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Hautklinik, Münster**

Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2014/05/01**
- Target Sample Size: **100**
- 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

Diagnosis of notalgia paraesthetica or brachioradial pruritus with actual therapy need

Exclusion criteria

Exclusion.

1.current and past (last 2 weeks) use of topical or systemic pain modulators (e.g.,

Addresses

■ **Primary Sponsor**

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Sources of Monetary or Material Support

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

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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.*