Trial Description

Title

Quality of life and treatment satisfaction with conventional systemic therapy in patients with psoriasis vulgaris - an observational study.

Trial Acronym

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URL of the trial

[---]*

Brief Summary in Lay Language

The aim of this observational study is to find out what effect therapy with systemic conventional drugs (eg Fumaderm , MTX or Apremilast) has, in terms of the quality of life of patients with psoriasis, and how satisfied they are with the treatment.

Participants are immediately asked, after the initiation of therapy with a systemic conventional medicine (eg Fumaderm,MTX or Apremilast) and after 4 , 12 and 24 weeks, to fill out two questionnaires. For this they need about three minutes .

Furthermore, no additional measures are carried out, merely recorded data that is recorded in terms of medical care, is evaluated.
The survey, with the two questionnaires will be conducted during routine inspections.

Brief Summary in Scientific Language

This is a prospective, non-interventional observational study to evaluate treatment satisfaction and quality of life in patients with psoriasis who begin therapy with one of the common non-biological systemic agents (Apremilast, Methotrexate or Fumaderm). The study is conducted at the studycenter in the Department of Dermatology at the University of Heidelberg.

The conventional systemic therapy with methotrexate and Apremilast, Fumaderm is highly effective in patients with psoriasis vulgaris. All three drugs have been approved in Germany for the treatment of psoriasis.

Patient satisfaction with respect to the drug of choice is of utmost importance as it is beneficial to the patient´s compliance and preservation of the therapy.

To date, there is no study to evaluate patient satisfaction and quality of life in psoriasis patients with a conventional systemic therapy (Apremilast, methotrexate and Fumaderm). In this study, this issue will be evaluated for the first time.

Organizational Data

- DRKS-ID: **DRKS00008721**
- Date of Registration in DRKS: **2015/10/19**
- 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.: **S-298/2015 , Ethik-Kommission I der Medizinischen Fakultät Heidelberg**

Secondary IDs

- Universal Trial Number (UTN): **U1111-1172-6860**

Health condition or Problem studied

- ICD10: **L40.0 - Psoriasis vulgaris**

Interventions/Observational Groups

- Arm 1: **Patients with initiation of therapy with MTX (methotrexate) - Evaluation of skin condition and 2 patient questionnaires in follow up.**
- Arm 2: **Patients with initiation of therapy with Fumaderm- Evaulation of skin condition and two patient questionnaires in follow up.**
- Arm 3: **Patients with initiation of therapy with apremilast -Evaulation of skin condition and two patient questionnaires in follow up.**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **Non-randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Active control (effective treament of control group)**
- Purpose: **Treatment**
- Assignment: **Other**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **No**

Primary Outcome

The aim of this study is to provide the quality of life, in the first 6 months of treatment, measured with the DLQI questionnaire and to compare these - in patients with conventional systemic therapies, with the approved drugs (Apremilast, methotrexate, Fumaderm).

Secondary Outcome

The aim of this study is it furthermore in the first 6 months of Treatment, to measure and compare treatment satisfaction with the TSQM questionnaire - in patients with conventional systemic therapies (Apremilast, MTX, Fumaderm)

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Hautklinik, Heidelberg**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2015/10/30**
- Target Sample Size: **60**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **99 Years**

Additional Inclusion Criteria

Patients with plaque psoriasis who begin therapy with a conventional systemic drug (Apremilast, methotrexate or Fumaderm) at the Department of Dermatology at the University of Heidelberg.

Patients must be at least 18 years old and give their written consent for study participation.

Exclusion criteria

Patients who are younger than 18 years of age, or are not fluent of the German language.
Furthermore, patients with psychiatric diagnoses are excluded.

Addresses

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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): **2016/03/31**

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.*