Trial Description

Title

Influence of Medical Rehabilitation on Quality of Life in Patients with Chronic Myeloid Leukemia (CML)

Trial Acronym

REHA-CML

URL of the trial

http://www.rehaklinik-thueringen.de

Brief Summary in Lay Language

**Major Goal: Investigation, if and how much quality of life can be improved by medical rehabilitation in patients with chronic myeloid leukemia (CML).
Background: Up to now, no data are available which show an improved quality of life induced by medical rehabilitation in patients with CML.
Methods: Evaluation of standardised and validated questionaries at the beginning, the end and one year after rehabilitation
Study participants: patients with or after CML who are in the Masserberger Klinik (Thueringen, Germany) for medical rehabiltation
Aims: Evaluation of alterations of the quality of life by medical rehabilitation
Hypothesis: a significant improvement of the quality of life can be achieved by an appropriated medical rehabilitation.**

Brief Summary in Scientific Language

Evaluation of the quality of life using standardised and validated questionaries (e. g. EORTC-QLQ C30 and EORTC-QLQ-CML24) at the beginning, the end and one year aftre rehabilitation; statisitcal evaluation of the questionaries.

Do you plan to share individual participant data with other researchers?

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00005385**
- Date of Registration in DRKS: **2014/01/07**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***

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- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **44421/2013/150 , Ethikkommission der Landesärztekammer Thüringen**

Secondary IDs

- Universal Trial Number (UTN): **U1111-1149-8643**

Health condition or Problem studied

- ICD10: **C92.1 - Chronic myeloid leukaemia**

Interventions/Observational Groups

- Arm 1: **Patients with or after CML are asked to answer the quality of life questionary at the beginning of the rehabilitation, at the end and one year thereafter**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **Single arm study**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Uncontrolled/Single arm**
- Purpose: **Supportive care**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Improvement of the quality of life is determined by evaluation of the EORTC questionaries (EORTC-QLQ 30 und EORTC QLQ-CML24). Timepoints: at the beginning of the rehabilitation, at the end and one year thereafter

Secondary Outcome

/

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Medical Center **Rehabilitationsklinik , Masserberg**

Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2014/01/20**
- Target Sample Size: **50**
- 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 or after CML, i. e. under treatment or after treatment because of CML

Exclusion criteria

Patients withour CML; patients who do not participate in a medical rehabilitation or who do not want to participate in the study.

Addresses

■ **Primary Sponsor**

Masserberger Klinik Prof. Volhard - Prof. Georg Lenz
Mr. PD Dr. med. Andreas Willer
Hauptstrasse 18
98666 Masserberg
Germany

Telephone: **03687081590**
Fax: **03687081199**
E-mail: **a.willer at rehaklinik-thuerigen.de**
URL: **[---]***

■ **Contact for Scientific Queries**

Masserberger Klinik Prof. Volhard - Prof. Georg Lenz
Mr. PD Dr. med. Andreas Willer
Hauptstrasse 18
98666 Masserberg
Germany

Telephone: **03687081590**
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■ **Contact for Public Queries**

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Mr. PD Dr. med. Andreas Willer
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98666 Masserberg
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Telephone: **03687081590**
Fax: **03687081199**
E-mail: **a.willer at rehaklinik-thueringen.de**
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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 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.*