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

Trial Description

Title

d-LIVER - The Potential for Community Monitoring as a Tool to Improve Clinical Care and Patient Quality of Life in Advanced Liver Disease

Trial Acronym

QoLIVER

URL of the trial

http://www.charite.de/avt/forschung/workgroup_for_the_liver/ongoing-projects.html ODER: http://www.d-liver.eu/

Brief Summary in Lay Language

Increasing importance of psychosocial health has put disease related quality of life in the focus of an integrated medical approach. Health related quality of life (HRQoL) has been shown to be reduced in patients with chronic liver disease when compared to normal healthy population. However, the course of HRQoL in this chronic disease has not been analyzed sufficiently so far. Beyond that the real impact of common complication in chronic liver failure patients (ascites, episodes of hepatic encephalopathy (HE)) on life quality has not been determined sufficiently. In this prospective multicentric bi-national study, we collect 2-monthly data on health related quality of life over 1 your of patients with chronic liver disease.

Brief Summary in Scientific Language

The project aim of d-LIVER is to develop a complete solution for remote ICT-enabled home monitoring of chronic liver failure patients. Development of such management concepts and implementation of telemedical solutions could detect deterioration in health status and controlled by swift and beneficial treatment. Thus potentially such episodes could be more effectively foreseen and prevented. This might result in an increasingly efficient treatment of chronic liver failure and in turn influence HRQoL and survival. Health related quality of life (HRQoL) has been shown to be reduced in patients with chronic liver disease when compared to normal healthy population. However, the course of HRQoL in this chronic disease has not been analyzed yet. Beyond that the real impact of common complication in chronic liver failure patients (ascites, episodes of hepatic encephalopathy (HE)) on life quality has not been determined sufficiently. Study participants will be recruited from in-patient and out-patient cohorts at Charité-University. Every two month patients will complete disease specific (e.g CLDQ) and generic questionnaires (e.g. SF-36) over 1 year. To determine long-term survival (e.g. 3 and 5 year survival) clinical data will be collected until 5 years after study enrollment. In addition actual enzymatic liver function capacity will be analyzed at the time of enrolment using the LiMAx test and liver specific tests.

Organizational Data

- DRKS-ID: **DRKS00005308**
- Date of Registration in DRKS: **2013/09/16**
- 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.: **EA1/111/13 , Ethik-Kommission der Charité - Universitätsmedizin Berlin-**

Secondary IDs

Health condition or Problem studied

- ICD10: **K71.9 - Toxic liver disease, unspecified**
- ICD10: **K72.1 - Chronic hepatic failure**

Interventions/Observational Groups

- Arm 1: **Study participants will be recruited from in-patient and out-patient cohorts at Charité-University. Liver disease patients At inclusion blood parameters, liver tests (ICG, LiMAx and FibroScan) will be performed. HRQoL will be captered every 2 month over at least 1 year. Moreover clinical data on survival and or transplantation will be recorded over a period of up to 5 years. In case of deterioration of the health status testings will be repeated.**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Other**
- Allocation: **Single arm study**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Uncontrolled/Single arm**
- Purpose: **Health care system**
- Assignment: **Single (group)**
- Phase: **N/A**

Study Type: **Non-interventional**

Study Type Non-Interventional: **Other**

Allocation: **Single arm study**

Blinding: **[---]***

Who is blinded: **[---]***

Control: **Uncontrolled/Single arm**

Purpose: **Health care system**

Assignment: **Single (group)**

Phase: **N/A**

- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

The study will address the following specific question: What is the specific contribution made by the presence of the potentially treatable complications of ESLD encephalopathy and ascites to impairment of quality of life and function? The data in the literature suggest associations between the specific complications and impaired QOL, but does this suggest enhanced treatment for the complications would result in improved overall QOL

Secondary Outcome

- Influence of disease severity and actual liver function on HRQoL
- Identification of prognostic markers of short and longtime survival in patients with chronic liver disease

Countries of recruitment

- DE **Germany**
- UK **United Kingdom**

Locations of Recruitment

- Medical Center **Charité - Universitätsmedizin Berlin, Berlin**
- University Medical Center **Hospitals, Newcastle**

Recruitment

- Planned/Actual: **Actual**

Planned/Actual: **Actual**

- (Anticipated or Actual) Date of First Enrollment: **2012/08/01**
- Target Sample Size: **400**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

Inclusion Criteria: - patient age >= 18 years - Biopsy proven cirrhosis - OR Suspected cirrhosis with existing complications like Varices, Ascites or Encephalopathy or increased liver tissue. - patients given written informed consent

Exclusion criteria

Exclusion Criteria 1. Malignancy (excluding HCC) 2. Current antivirals for HCV

Addresses

- **Primary Sponsor**

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Sources of Monetary or Material Support

■ **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

Europäische Kommission, Seven Framework Programme (Projektnummer 287596)
Rue de la Loi / Wetstraat 200
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E-mail: **[---]***
URL: **[---]***

Status

- Recruitment Status: **Recruiting complete, follow-up continuing**
- 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.*