

Trial Description

Title

Comparison of selenium levels in HCV- infected patients at different stages of disease

Trial Acronym

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URL of the trial

[---]*

Brief Summary in Lay Language

The incidence of hepatocellular carcinoma (HCC) is rising worldwide. One important etiology is a chronic inflammation due to hepatitis c infection. Over the steps of a chronic inflammation over the stadium of liver cirrhosis it is possible that neoplastic nodules appear in the liver which can rise up to a HCC. In the pathogenesis of HCC oxidative stress seems to play an important role and as selenium is a key micronutrient in this process its levels could differ between the different stages of disease in hcv- infected patients. The aim of this study is to examine these differences.

amendmend 02/2012: In order to compare selenium levels in patients with chronic liver disease due to HCV infection, 10 healthy, age-matched controls were included in the analyses.

Brief Summary in Scientific Language

The incidence of hepatocellular carcinoma (HCC) is rising worldwide. Almost all cases of HCC develop over clearly defined stages of chronic hepatic inflammation and cirrhosis of the liver which can be determined as an irreversible stage during this process. In the Western world excessive alcohol consumption and chronic infection with the hepatitis c virus are frequent causes of chronic hepatocellular injury. As HCC is often diagnosed at advanced stages and therapeutic intervention possibilities are limited it becomes more and more necessary to search for prevention strategies to stop the development of HCC.

In the last years micronutrients such as selenium have reached the interests of oncologists. Several studies were able to show that there are often low selenium levels in patients with different tumors. Some epidemiologic studies showed that supplementation of selenium can decrease the incidence of some tumors. Oxidative stress is meant to play an essential role in hepatocarcinogenesis and as selenium could decrease it, it may be possible that patients infected with the hepatitis c - virus show low selenium levels probably as a result of the chronic hepatic inflammation. Moreover there may be differences between the stages of disease namely chronic infection, cirrhosis of the liver and hepatocellular carcinoma. The aim of this trial is to determine these differences.

Organizational Data

- DRKS-ID: **DRKS00000813**
- Date of Registration in DRKS: **2011/04/27**
- Date of Registration in Partner Registry or other Primary Registry: **2011/05/06**
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **146/11 , Ethik-Kommission der Albert-Ludwigs-Universität Freiburg**

Secondary IDs

- Primary Registry-ID: **NCT01355107 (Clinical Trials)**

Health condition or Problem studied

- ICD10: **C22.0 - Malignant neoplasm: Liver cell carcinoma**
- ICD10: **K73.9 - Chronic hepatitis, unspecified**

Interventions/Observational Groups

- Arm 1: **observation group: patients with cronic hcv- infection without cirrhosis of the liver and without HCC (10 patients)**
- Arm 2: **observation group: patients with hcv- infection with cirrhosis of the liver, but without HCC (10 patients)**
- Arm 3: **observation group: patients with hcv- infection with HCC (10 patients)**
- Arm 4: **observation group: healthy controls (10 controls)**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **Non-randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Other**
- Purpose: **Treatment**
- Assignment: **Parallel**
-

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Assignment: **Parallel**

Phase: **N/A**

- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

comparison of the selenium levels in these 4 groups

Secondary Outcome

- **selenium levels and inflammatory activity**
- **selenium levels and stadium of HCC**
- **selenium levels and MELD(Na)score**

Countries of recruitment

- **DE Germany**

Locations of Recruitment

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2011/04/13**
- Target Sample Size: **40**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Male**
- Minimum Age: **18 Years**
- Maximum Age: **80 Years**

Additional Inclusion Criteria

- a) patients with chronic hepatitis c- infection: no cirrhosis of the liver (= Desmet IV), no HCC - suspected lesion in the liver
- b) patients with hcv- associated cirrhosis of the liver: - cirrhosis of the liver confirmed by ultrasound, CT/MRI imaging or biopsy, all child - stages
- c) patients with hcv- associated HCC: diagnosis of HCC according to the AASLD criteria, HCC has not been treated at the time of enrollment, all BCLC- /UICC- stages.
- d) for all three groups: diagnosis of the chronic hcv- infection with virus rna and serologic parameters (anti-hcv) and abnormal liver function for more than 6 months, no antiviral treatment during the last 6 months

Exclusion criteria

- application of dietary supplements
- excessive alcohol consumption
- all other etiologies leading to a liver injury
- patients with an acute-phase- reaction (SIRS, sepsis, patients in intensive care units)
- extrahepatic neoplasm
- rheumatic disease apart from hcv- associated immunologic phenomena
- diabetes mellitus I and II
- immunological diseases

Addresses

■ Primary Sponsor

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■ Contact for Scientific Queries

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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): **2012/06/30**

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2011/05/06

Trial Publications, Results and other documents

- Paper **Bettinger D. et al., Selenium levels in patients with hepatitis C virus-related chronic hepatitis, liver cirrhosis, and hepatocellular carcinoma: A pilot study.** *Hepatology*. 2013 Jun;57(6):2543-4.

* *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.*