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

Trial Description

Title

Clinical trial investigating the role of vitamin D in the treatment of depression in patients with chronic liver disease

Trial Acronym

CLDVitD Trial

URL of the trial

[---]*

Brief Summary in Lay Language

This study assesses whether depressive symptoms improve after vitamin D replacement therapy in patients with chronic liver disease and vitamin D deficiency. We gave vitamin D supplements to patients with chronic liver disease and vitamin D deficiency. Those with no vitamin D deficiency received no supplements. We hypothesise that depressive symptoms will improve once vitamin D levels increase following supplementation with vitamin D.

Brief Summary in Scientific Language

Patients with chronic liver diseases regularly suffer from vitamin D deficiency and depression. A recent meta-analysis reported an inverse correlation between depression and vitamin D levels. Indeed, vitamin D receptor is present and genomic and nongenomic vitamin D receptor-mediated signalling has been described in brain. This intervention study investigates whether vitamin D therapy ameliorates depressive symptoms in chronic liver disease patients.We hypothesise that depressive symptoms will improve upon vitamin D replacement therapy.

Organizational Data

- DRKS-ID: **DRKS00007782**
- Date of Registration in DRKS: **2015/02/05**
- 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.: **57/11 , Ethik-Kommission bei der Ärztekammer des Saarlandes**

Secondary IDs

- Universal Trial Number (UTN): **U1111-1166-9516**

Health condition or Problem studied

- ICD10: **F32 - Depressive episode**
- ICD10: **K70-K77 - Diseases of liver**

Interventions/Observational Groups

- Arm 1: **Vitamin D supplements (20,000 IU Dekristol p.o. daily for 7 days, thereafter weekly) for 6 months**

  Patients: with chronic liver disease and vitamin D deficiency with or without depression. We created subgroups based on presence of depressive symptoms.
- Arm 2: **Patients with normal vitamin D levels were followd up during the same time periods, but were not given any vitamin D supplelments.**

  Patients: with chronic liver disease with or without depression, but not vitamin D deficiency.

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Non-randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Other**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Changes to depressive symptoms after 3 and 6 months of vitamin D supplementation, as assessed using the BDI-II instrument

Secondary Outcome

Changes to serum liver function tests (ALT, AST, AP, GGT, Bilirubin, Albumin) after 3 and 6 months, as assessed using standard clinical-chemical assays

changes to bone density after 12 months, assessed using Dexa scans

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Saarland University Medical Center, Homburg**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2011/12/15**
- 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: **no maximum age**

Additional Inclusion Criteria

- men and women
- over 18 years of age
- chronic liver disease

Exclusion criteria

- severe hepatic encephalopathy (CFF <35 Hz)
- Interferon treatment
- hypercalcaemia (>2.7 mmol/l) or hypercalciuria (>8.0 mmol/d) with or without hyperparathyroidism (>65.0 pg/ml)
- history of calcium-containing kidney stones
- allergy or hypersensitivity to any of the supplement ingredients: peanuts, soy, gelatin
- sarcoidosis
- stage IV or V Chronic Kidney Disease

- Pregnancy

Addresses

■ **Primary Sponsor**

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66421 Homburg
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Sources of Monetary or Material Support

■ **Institutional budget, no external funding (budget of sponsor/PI)**

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E-mail: **frank.lammert at uks.eu**
URL: **[---]***

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2013/12/19**

Trial Publications, Results and other documents

- Paper **Journal site**

** 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.*