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

Trial Description

Title

Probiotic supplementation in patients with chronic liver disease, resulting from the hepatitis C virus

Trial Acronym

ProbioC

URL of the trial

[---]*

Brief Summary in Lay Language

Patients with chronic liver disease/hepatitis C virus infection frequently present with depressive symptoms, the prevalence of which appears to be higher compared to chronic liver disease of other aetiologies. This intervention study investigates whether probiotic supplementation improves depressive symptoms in patients with the chronic hepatitis C virus.

Our hypothesis: probiotic supplementation improves depressive symptoms in patients with the chronic hepatitis C virus infection.

Brief Summary in Scientific Language

Patients with chronic liver disease are at increased risk for depressive and cognitive disorders, which have a strong influence on the quality of life. Pharmacological treatments for depression are not always effective, and some patients are not willing to take psychiatric drugs because they fear the side effects. Experimental studies have shown specific strains of intestinal bacteria to positively influence brain neurotransmitters which are implicated in depression. Moreover, clinical studies have shown that psychological distress and depressive symptoms can be alleviated by probiotic supplementation. Dysbiosis has been confirmed in patients with chronic liver disease and the hepatitis C virus infection. Treatment with antidepressants needs to be avoided in certain patients, because of the risk of adverse liver-related effects. We therefore want to perform a controlled study to investigate the role of probiotic supplementation for 60 days in depressive symptoms in patients with chronic hepatitis C virus infection.

Organizational Data

- DRKS-ID: **DRKS00007817**
- Date of Registration in DRKS: **2015/02/16**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***

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Date of Registration in DRKS: **2015/02/16**
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- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **27/13 , Ethik-Kommission bei der Ärztekammer des Saarlandes**

Secondary IDs

- Universal Trial Number (UTN): **U1111-1167-2354**

Health condition or Problem studied

- ICD10: **F32 - Depressive episode**
- ICD10: **B18.2 - Chronic viral hepatitis C**

Interventions/Observational Groups

- Arm 1: **The intervention group receives the probiotic strains (lactobacillus helveticus and Bifidobacterium Longum) p.o. once a day for 60 days. At 30 and 60 days, patients will be assessed for severity of depressive and stress symptoms using the BDI-II and the PSS.**
- Arm 2: **The control group receives an identical placebo p.o. once a day for 60 days.**
  At 30 and 60 days, patients will be assessed for severity of depressive and stress symptoms using the BDI-II and the PSS.

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **patient/subject, investigator/therapist, assessor, data analyst**
- Control: **Placebo**
- Purpose: **Treatment**
- Assignment: **Parallel**
-

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Control: **Placebo**

Purpose: **Treatment**

Assignment: **Parallel**

Phase: **N/A**

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

Primary Outcome

change in depression score using BDI-II from baseline to 30 and 60 days (after probiotic I placebo supplementation).

Secondary Outcome

- changes in intestinal flora after 30 and 60 days of probiotic/placebo supplementation
- changes in serum LFTS (ALT, AST, AP, GGT, Bilirubin, Albumin) after 30 and 60 days of a probiotic/placebo supplementation

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: **2013/07/10**
- Target Sample Size: **30**
- 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

Patients with the chronic hepatitis C virus infection and depression

Exclusion criteria

- Severe hepatic encephalopathy (i.e. CCF score <35 Hz)
-Women who are pregnant or breastfeeding
-Immunocompromised patients (as assessed by noting those taking immunosuppressive treatment or those with a known HIV infection)
-Receiving depression-focused psychotherapy less than eight weeks of screening
-Another diagnosis of mental illness
-At risk of / or actively suicidal (assessed with BDI-II and by a pyschiatrist if needed)
-Interferon therapy
-Cirrhosis (ie, Fibroscan score > 16)
-Intake of pre or probiotic products within previous four weeks
-Participation in a clinical trial with investigational drug/device during past month before enrolment

Addresses

- **Primary Sponsor**

  Lallemand Health Solutions, Institute Rosell Inc.
  H4P 2R2 Montreal
  Canada

  Telephone: **[---]***
  Fax: **[---]***
  E-mail: **[---]***
  URL: **[---]***

- **Contact for Scientific Queries**

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Sources of Monetary or Material Support

- **Commercial (pharmaceutical industry, medical engineering industry, etc.)**

Lallemand Health Solutions, Institute Rosell Inc.
6100, avenue Royalmount
H4P2R2 Montreal
Canada

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

Status

- Recruitment Status: **Recruiting stopped after recruiting started**
- Study Closing (LPLV): **2016/04/17**

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.*