

10.

PBC Induced Fatigue Treated With Thiamine (PIFT)

Background/aims:

Primary biliary cholangitis (PBC) is a chronic autoimmune liver disease characterised by destruction of the intrahepatic bile ducts leading to liver inflammation and fibrosis, and ultimately liver cirrhosis and end-stage liver disease. More than 50% of patients with PBC suffer from chronic fatigue, and approximately 20% suffer from severe fatigue with negative impact on their quality of life. Although fatigue is a large problem in patients with PBC, no effective treatments are available. A Danish intervention study have shown that high dose oral thiamine (Vitamin B1) were effective in treating chronic fatigue in patients with inflammatory bowel disease. In this study, only few and minor adverse events to thiamine treatment were observed. Although the precise mechanism of work remains unknown, the investigators see no reason that this cannot be transferred to patients with PBC. Hence, the investigators aim to conduct a study investigating the use of oral thiamine in chronic fatigued patients with PBC.

Study design/Methods or/PROMS:

The study will be conducted as a double-blinded, placebo-controlled, randomised, crossover trial including 36 patients with PBC and with a higher fatigue level than in the general population for more than six months.

The patients will be randomised into one of two 3x4 weeks setups; 1) thiamine for four weeks followed by four-week washout and finally four weeks of placebo or 2) placebo for four weeks followed by four-week washout and finally four weeks of thiamine.

The primary endpoint is to investigate the fatigue-level before and after treatment with thiamine and placebo using every patient as their own control.

Fatigue-level will be measured using international validated questionnaires (PBC-40 and EQ5D).

The doses of thiamine (600 – 1800 mg/day) are calculated based on the patient gender and weight.

Target population: 36 patients with PBC and with a higher fatigue level than in the general population for more than six months. All patients will be included in the outpatient clinic at the Department of Hepatology and Gastroenterology at Aarhus University Hospital, Denmark.

Languages: Danish.

Countries: Aarhus University Hospital, Denmark.

Inclusion and exclusion criteria:

Inclusion: Adult patients with PBC and with a higher fatigue level than in the general population for more than six months (chronic fatigue).

Exclusion: Fatigue due to other conditions.

Study period/begin/stage: Inclusion start May 2021 – inclusion end June 2022. Last patient - last visit, Sep. 2022.

Open for inclusions: No

Contact details:

PI, Henning Grønbaek: henning.gronbaek@aarhus.rm.dk

Sub-investigators:

Lars Bossen: larsboss@rm.dk

Palle Bager: pallbage@rm.dk

Rasmus Gantzel: ragant@rm.dk