EudraCT Number: 2020-001173-69
Title: Impact of LTBI Treatment on Glucose Tolerance and Chronic Inflammation
Sponsor: Pernille Ravn
Study Phase: IV
Study Start Date: April 04, 2021
Study End Date: May 01, 2023
Trial Status: Terminated early

Reason for early termination:

In this trial, we aimed to include 20 persons with a latent tuberculosis infection (LTBI) and DM in one arm and 20 persons with LTBI only in another arm. As a consequence of COVID-19, the trial was terminated prematurely due to low inclusion rates. At termination, only 10 individuals had participated in oral glucose tolerance tests (OGTTs) before and after treatment. We here present the results from these individuals.

Objective:
The objective of this study was to investigate if treatment of TBI affects glucose metabolism, body composition and inflammation in persons with or without type 2 diabetes mellitus.

Methodology:
A 75-g oral glucose tolerance test (OGTT), dual-energy X-ray absorptiometry, bioimpedance and blood sampling for inflammatory biomarkers were performed before and after treatment for TBI.

Results:

Table 1. Clinical characteristics of the participants with complete OGTT data.

	LTBI (n=10)
Characteristics	
Age (years)	55.9 (14.2)
Sex (males) n (%)	4 (40%)
Known type 2 diabetes n (%)	0 (0.0%)

Baseline characteristics. Data are presented as means (standard deviation) or n (%).

After treatment, no significant changes were seen in the AUC for Glucose, C-peptide AUC or insulin. The inflammatory biomarkers CRP, IFN-γ, TNF-α and IL-6 and body composition measures were also unchanged.

Some individuals in this cohort also had thrombelastography performed before and after treatment. These individuals were pooled with data from another study. The pooled data are published: https://doi.org/10.1186/s12959-024-00625-4

Adverse events:

A total of 12 participants received trial medication. A total of 5 AEs and 1 SAE were reported by three participants.

AE 1 and 2:

One participant had 2 AEs in the form of mildly low potassium levels.

SAE:

The same participant visited the emergency department (ED) due to vomiting and abdominal discomfort. The participant was discharged from the ED in under 24 hours but the event was still documented as an SAE. In the end, the event was deemed to be caused by a viral abdominal infection and thus not a SAR.

One participant fell and was therefore briefly evaluated at the ED. The patient was observed for 12 hours and was discharged without any symptoms. The fall was not associated in any way to the study drugs

AE 3:One participant was admitted to the emergency department due to a fall and was observed for 12 hours. The fall was not related to the study medication.

AE 4: One participant experienced elevated liver enzymes, enzymes reverted to normal values after treatment stop.

AE 5: One patient experienced decreased appetite, mild abdominal discomfort and nausea. The symptoms reverted after treatment stop.

Conclusion:
We did not observe any impact of LTBI treatment on glucose metabolism or inflammation in a cohort which was severely underpowered. No safety concerns regarding the drugs used were identified.

On behalf of sponsor Pernille Ravn,

Niklas Lorentsson