Cover Page:

Study Title: Prognostic Relevance of Fatty Liver Disease for Patients with Chronic Hepatitis B

Short Title: Steatohepatitis in Chronic Hepatitis B

Date: December 31st, 2021.

NCT number: not available.

Study Protocol:

Project title: Prognostic Relevance of Fatty Liver Disease for Patients with Chronic Hepatitis B

Project summary: Fatty liver disease is increasingly recognized in patients with chronic hepatitis B (CHB). Whether concurrent fatty liver disease affects the long-term outcomes of CHB is unclear. The investigators will perform a longitudinal study to investigate the prognostic relevance of concurrent fatty liver disease for patients with CHB receiving antiviral therapy.

Project description:

Rationale: Fatty liver disease has become more prevalent in individuals with CHB, owing to the obesity epidemic. The coexistence of CHB and fatty liver disease, particularly the histologic phenotype of steatohepatitis, can augment liver damage and increase the risk of liver fibrosis. However, there are limited data on the impact of fatty liver disease on clinical outcomes (e.g., cirrhotic complications, hepatocellular carcinoma, need for liver transplantation, and all-cause death) during comprehensive treatment for CHB.

Objectives: To determine the long-term effect of concurrent fatty liver disease, particularly a histologic phenotype of steatohepatitis on all-cause mortality and liver-related complications in patients with CHB receiving antiviral therapy at the Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok, Thailand.

Methodology: Retrospective analysis of a prospectively collected database of 408 patients with chronic HBV infection who underwent a liver biopsy for therapeutic decision in initiating antiviral therapy between 2002 and 2008 at Siriraj Hospital, Bangkok, Thailand.

Data management and analysis: Prospectively generated liver database that collates clinical, biochemical, and pathological data regarding chronic HBV infection and fatty liver disease. In addition, associated serological results, radiological reports, and patient follow-up/outcomes will

be also reported. Variables will be documented from the date of liver biopsy until either the study outcomes (death, liver transplantation, or liver-related complications), loss of follow-up, or the end of the study period.

Statistical analyses will be done using SPSS version 18.0. Quantitative variables will be compared between groups using standard parametric or non-parametric tests, and qualitative variables will be compared using the Chi-squared test. The cumulative probabilities of mortality or liver transplantation and liver-related complications will be estimated by the Kaplan-Meier method and compared by the log-rank test. Hazard ratios and 95% confidence interval estimates for the outcomes will be calculated by Cox proportional hazard models.

Ethical considerations: This study is approved by the Institutional Review Board and is conducted in accordance with the Declaration of Helsinki.

Gender issues: None

References

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