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Novel Diagnostic for Hepatitis

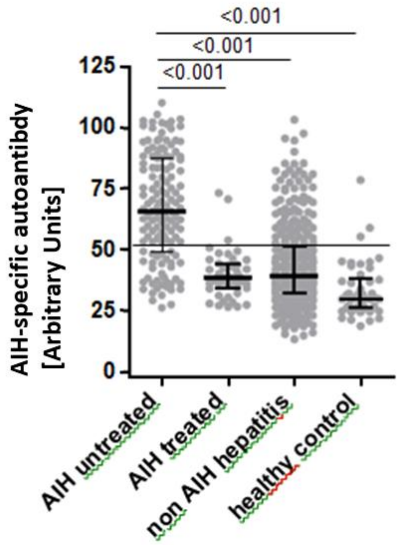
Keywords: Diagnosis, autoimmune Hepatitis, AIH, autoantibody, liver cirrhosis, prevention

INVENTION NOVELTY

Autoimmune Hepatitis (AIH) accounts for approximately 10% of chronic liver diseases. It is characterized by a chronic immune-mediated immune response against the patient's own liver leading to diverse clinical manifestations. Because of the ambivalence of symptoms diagnosis is primarily based on the exclusion of diseases with related characteristics. Without treatment there is a serious risk of disease progression to life-threatening liver cirrhosis with immediate need of liver transplantation. Here we present a novel autoantibody based diagnostic approach for the early prediction of AIH in pediatric and adult patients with a hepatitis of unknown etiology.

VALUE PROPOSITION

In 25%-80% of patients a remission can be achieved by a timely onset of therapy including normalization of aminotransferases and immunoglobulin G. Thus, there is a strong need for a specific diagnostic tool enabling the early differential diagnosis of AIH. Autoantibody tests to assess the likelihood of AIH are essential part of the work-up of all liver diseases beyond viral hepatitis. The MHH inventors meet this challenge with this new diagnostic method to provide a tool for an early diagnosis of AIH.



Novel AIH-specific autoantibody enables differential diagnosis of AIH and therapy control.

TECHNOLOGY DESCRIPTION

The technology is based on a recently identified autoantibody which is highly predictive for AIH. Analysis of a serum or plasma sample of a suspect patient (e.g. by ELISA) enables the timely diagnosis of AIH. Interestingly, the novel AIH specific autoantibody enables also the differential diagnosis between AIH and other liver diseases. In conclusion, the technology comprises a reliable and specific tool for the early diagnosis of AIH and the timely onset of therapy. Moreover, further studies demonstrated that the novel antibody represents a valuable tool to diagnosed AIH, when conventional autoantibodies are not detectable.

COMMERCIAL OPPORTUNITY

In-licensing or collaboration for further development is possible.

DEVELOPMENT STATUS

Initial proof-of-concept studies have been performed with ELISA prototypes and clinically relevant samples.

PATENT SITUATION

Patent has been granted in Europe (EP 3701264B1, national validation in DE, CH, FR and GB) with priority of 2017.

US patent application (US 16/754,006) based on international application WO 2019/081692 A1 is pending.

FURTHER READING

Taubert R, Engel B, Diestelhorst J, Baerlecken NT, Manns M, Jaeckel E. 2021.Quantification of polyreactive immunoglobulin G facilitates the diagnosis of autoimmune hepatitis. Hepatology. doi: 10.1002/hep.32134.

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