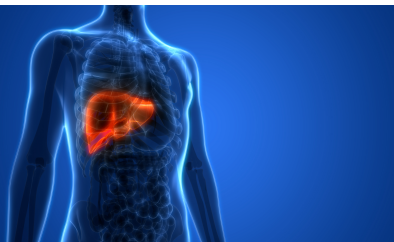


Novel clinical biomarker for hepatic steatosis

The worldwide rise of obesity and metabolic syndrome has led to an increasing prevalence of nonalcoholic fatty liver disease. A subset of the one-quarter of affected patients globally have nonalcoholic fatty liver disease nonalcoholic steatohepatitis, which is an inflammatory disease that often advances to cirrhosis and end-stage liver failure. The enormous number of affected patients is accompanied with substantial morbidity, mortality and healthcare costs, presenting an emerging clinical challenge.

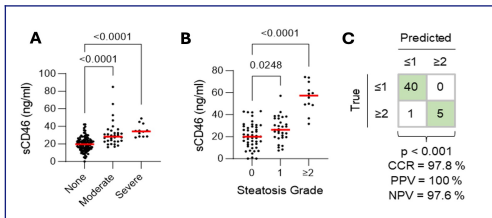


Soluble CD46 in plasma as a predictor of hepatic steatosis

Determining soluble CD46 levels in human blood serves as a reliable, noninvasive biomarker for diagnosis and treatment monitoring of hepatic steatosis.

REFERENCES:

↓ Bitterer et al., 2024_Lancet



A) Patients with moderate or severe steatosis (by ultrasound) have higher sCD46 levels than those with no clinically relevant steatosis. **B)** sCD46 levels in plasma from patients with liver malignancies. Steatosis assessment by histology. Grade ≤ 1 corresponds to ultrasound diagnosis of no clinically relevant steatosis. **C)** Cross-tabulation of predicted steatosis grade in validation set patients considering only most clinically relevant distinction between Grade ≤ 1 and ≥ 2 .

IP RIGHTS

PCT filed, EP and US pending

2024

CHALLENGE

Fatty liver disease constitutes a significant challenge in modern healthcare. Early stage intervention improves prognosis, but there is a lack of cost-effective and noninvasive diagnostic tests for detecting and staging hepatic steatosis. Presently, diagnosis depends on resource-intensive imaging by abdominal ultrasound or MRI, which sometimes must be followed up by liver biopsy.

INNOVATION

Shedding of CD46 from hepatocytes into circulation reflects a stress response of hepatocytes to fat loading, which appears to be connected with activation of innate-like lymphocyte responses; therefore, soluble CD46 is unlike other established clinical liver markers by measuring a different type of hepatocyte property indicating cell injury, synthetic function, detoxifying activity, fibrosis or systemic inflammation. Soluble CD46 is a promising clinical marker of patients with steatosis at risk of developing early liver inflammation, a prevalent subset that could benefit from earlier clinical detection and intervention.

01 Basic principles observed · 02 Technology concept formulated · 03 Experimental proof of concept · 04 Technology validated in lab · 05 Technology validated in relevant environment · 06 Technology demonstrated in relevant environment · 07 System prototype demonstrated in operational environment · 08 System complete and qualified

TRL 08

TRL 07

TRL 06

TRL 05

TRL 04

TRL 03

TRL 02

TRL 01

Technology Readiness Level (TRL)



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