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Non-invasive tests to safely avoid screening endoscopy in patients with liver cirrhosis in Kuwait

Submission date
15/07/2026

Recruitment status
No longer recruiting

Registration date
16/07/2026

Overall study status
Completed

Last Edited
16/07/2026

Condition category
Digestive System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Cirrhosis (liver scarring) can cause enlarged veins in the food pipe, called varices, which may bleed. Doctors usually screen for these with a camera test (endoscopy), but many patients turn out to be at low risk and gain nothing from the test. This study looked at whether two simple, non-invasive measurements, a FibroScan (a painless scan of liver stiffness) and a routine blood platelet count, can safely identify which patients can avoid endoscopy. It focused on patients whose cirrhosis is linked to fatty liver disease, including those with obesity, in a Kuwaiti (Gulf Arab) population where these criteria had not been tested before.

Who can participate?
Adults aged 18 years and over with early-stage (compensated) cirrhosis who were undergoing routine liver assessment

What does the study involve?
Participants had the tests that are already part of their routine care: a FibroScan, a blood test for platelet count, and an upper endoscopy. The non-invasive measurements were compared against the endoscopy findings to see how reliably they identify patients with high-risk varices so that endoscopy could be safely avoided in the future. No extra procedures, medicines, or samples were added for the study.

What are the possible benefits and risks of participating?
Participants may not benefit directly. The findings may help doctors decide which patients with cirrhosis can safely avoid unnecessary endoscopy in the future. There were no additional risks beyond the routine tests participants were already having.

Where is the study run from?
Al Adan Hospital (Kuwait)

When is the study starting and how long is it expected to run for?
January 2022 to April 2026

Who is funding the study?
Al Adan Hospital (Kuwait)

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Study information

Scientific Title
Baveno VII endoscopy-sparing criteria in MASLD-predominant compensated cirrhosis: a prospective validation from a Gulf Arab population (Kuwait)

Acronym
BAVENO-KW

Study objectives
To prospectively evaluate whether the Baveno VII non-invasive criteria (liver stiffness measurement by transient elastography plus platelet count) can safely identify patients with compensated cirrhosis who may avoid screening endoscopy for high-risk oesophageal varices, with pre-specified analysis by MASLD and obesity status, and to externally assess the ANTICIPATE-NASH model for predicting clinically significant portal hypertension

Ethics approval required
Ethics approval required

Ethics approval(s)

Approved 04/01/2022, Research Ethics Committee (Ministry of Health, Kuwait, 13001, Kuwait; +965 (0)90069869; hkhamis@moh.gov.kw), ref: MOH/REC/060720221394

Primary study design
Observational

Secondary study design
Cohort study

Study type(s)

Health condition(s) or problem(s) studied
Compensated cirrhosis (compensated advanced chronic liver disease), predominantly due to metabolic dysfunction-associated steatotic liver disease (MASLD)

Interventions
Consecutive Kuwaiti adults with compensated cirrhosis underwent, within 3 months, vibration-controlled transient elastography (liver stiffness measurement and controlled attenuation parameter), a platelet count, and reference-standard upper gastrointestinal endoscopy performed by endoscopists blinded to elastography results. Baveno VI, Expanded Baveno VI, Baveno VII, and ANTICIPATE-NASH criteria were applied, with high-risk varices at endoscopy as the primary endpoint. Aetiology was classified per the 2023 multi-society MASLD nomenclature. Diagnostic performance (miss rate, negative predictive value, sensitivity, specificity) was calculated for the full cohort and by pre-specified subgroups (MASLD with obesity, MASLD without obesity, non-MASLD). Analyses used Wilson 95% confidence intervals, DeLong's method for ROC comparison, and multivariable logistic regression.

Intervention Type
Other

Primary outcome(s)
1. Presence of high-risk oesophageal varices measured using detection of high-risk varices (F2/F3 oesophageal varices, or any varix with high-risk stigmata) at upper gastrointestinal endoscopy, compared against the Baveno VII rule-out criterion (LSM <20 kPa and platelet count >150 × 10^9 /L); expressed as miss rate and negative predictive value; at enrolment (single timepoint; index endoscopy within 3 months of elastography)

Key secondary outcome(s)
1. Comparative performance of Baveno VI, Expanded Baveno VI, and Baveno VII criteria measured using the proportion of endoscopies spared and miss rate for each at enrolment

2. ANTICIPATE-NASH performance for clinically significant portal hypertension measured using positive predictive value versus LSM ≥25 kPa alone, with Hosmer–Lemeshow calibration, at enrolment

3. Optimal LSM threshold by subgroup measured using area under the receiver operating characteristic curve (AUROC) and Youden cutoff by DeLong's method at enrolment

Completion date
30/04/2026

Eligibility

Key inclusion criteria
1. Age ≥18 years
2. Kuwaiti nationality
3. Compensated cirrhosis (Child–Pugh A or B, no prior decompensation)
4. Liver stiffness measurement by vibration-controlled transient elastography within 3 months of index endoscopy
5. Concurrent platelet count within 3 months
6. Qualifying upper gastrointestinal endoscopy as reference standard
7. No prior non-selective beta-blocker therapy for portal hypertension prophylaxis
8. Written informed consent

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
120 Years

Sex
All

Total final enrolment
380

Key exclusion criteria
1. Decompensated cirrhosis
2. Active hepatocellular carcinoma or other malignancy
3. Portal vein thrombosis >50% luminal occlusion
4. Prior transjugular intrahepatic portosystemic shunt (TIPS) or surgical shunt
5. Prior endoscopic variceal band ligation
6. Technically unreliable liver stiffness measurement (LSM) (interquartile range/median >30% with LSM >7.1 kPa)
7. Acute-on-chronic liver failure

Date of first enrolment
06/01/2022

Date of final enrolment
30/04/2026

Locations

Countries of recruitment
Kuwait

Study participating centre
Al Adan Hospital
Gastroenterology and Endoscopy Department, Ministry of Health, Ahmadi Health Region
Kuwait

Sponsor information

Organisation
Adan Hospital

ROR
https://ror.org/01mtpwn71

Funder(s)

Funder type

Funder Name
Adan Hospital

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available