

# Study of the Efficacy and Safety of Nicotinamide in Patients With Liver Fibrosis (NICOFIB)

NCT06599918

---

Status	RECRUITING
Phase	Phase 2
Sponsor	Fundació Institut de Recerca de l'Hospital de la Santa Creu i Sant Pau
Enrollment	30 participants

## Key Eligibility Criteria

---

### Inclusion (4)

- Patients aged between 18 and 85 years.
- Diagnosis of non-alcoholic fatty liver disease (NAFLD) by their referring physicians (NAFLD defined as the presence of hepatic steatosis and in the absence of significant alcohol consumption, having excluded other liver diseases).
- BMI between 27-40 kg/m<sup>2</sup>.
- Fibroscan® value greater than 9.2 kPa, obtained within the last 6 months prior to the start of the study.

### Exclusion (30)

- Patients with any medical condition or illness that, in the opinion of the investigator, could interfere with the study results and/or affect the patients' ability to participate or complete the study.
- History of clinically significant heart disease (ejection fraction  $\leq 40\%$  [normal range 50-70%], heart failure defined as New York Heart Association [NYHA] Class  $\geq 2$ ; clinically significant congenital or acquired valvular disease; symptomatic coronary artery disease such as myocardial infarction or angina, history of unstable arrhythmias, history of atrial fibrillation).
- Decreased renal function (estimated glomerular filtration rate  $\leq 45$  mL/min/1.73 m<sup>2</sup>, calculated using the CKD-EPI formula) at screening.
- Alcohol consumption exceeding 30 g/day in men or 20 g/day in women.
- Patients with significant impairment of liver function in the selection analysis defined as repeated values of AST, ALT, and bilirubin  $\geq 3$  times the upper limit of normal.

... and 25 more (see full listing online)

## Locations (1 total)

---

Hospital de la Santa Creu i Sant Pau, Barcelona, Spain