

# Efficacy and Safety of Rifaximin-~~in~~ Treating MASLD

NCT07381257

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Status	RECRUITING
Phase	Early Phase 1
Sponsor	Shanghai Changzheng Hospital
Enrollment	60 participants

## Key Eligibility Criteria

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### Inclusion (9)

- Willingness to provide written informed consent.
- Aged 18 to 75 years, inclusive, regardless of gender.
- Diagnosis of hepatic steatosis (fatty liver) within the past 6 months.
- Presence of at least one metabolic/cardiovascular risk factor:
- A. BMI  $\geq$  23.0 kg/m<sup>2</sup>, or waist circumference  $\geq$  90 cm (male) / 80 cm (female). B. Fasting plasma glucose (FPG)  $\geq$  5.6 mmol/L, or 2-hour postprandial glucose  $\geq$  7.8 mmol/L, or HbA1c  $\geq$  5.7%, or documented history of type 2 diabetes mellitus (T2DM) or current use of anti-diabetic medication.

... and 4 more (see full listing online)

### Exclusion (22)

- Confirmed diagnosis of liver cirrhosis based on clinical, laboratory, imaging, and/or liver biopsy findings.
- Evidence of other specific etiologies of chronic liver disease confirmed by history or laboratory tests, including but not limited to: viral hepatitis (B or C, etc.), autoimmune liver disease, alcohol-related liver disease (defined as  $>$ 20 g/day for females or  $>$ 30 g/day for males), drug-induced liver injury, Wilson's disease, alpha-1 antitrypsin deficiency, or hereditary hemochromatosis.
- Other identifiable causes of hepatic steatosis confirmed by history or laboratory tests, such as: specific medications (e.g., tamoxifen, amiodarone, valproate, methotrexate, glucocorticoids, olanzapine), total parenteral nutrition, hypothyroidism, inflammatory bowel disease, Cushing's syndrome, celiac disease, abetalipoproteinemia, lipodystrophic diabetes, Mauriac syndrome, hypopituitarism, hypogonadism, polycystic ovary syndrome, etc.
- Use of medications known to alter gut microbiota (e.g., lactulose, systemic antibiotics, any intestinal microecological preparations) within 4 weeks prior to screening.
- Dose of hepatoprotective or lipid-lowering medications not stabilized for at least 4 weeks prior to screening.

... and 17 more (see full listing online)

## Locations (1 total)

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Changzheng Hospital, Naval Medical University, shanghai, China, Shanghai, China