

# An Efficacy and Safety Study of Akkermansia Muciniphila AKM Lab-01 in Hypercholesterolaemia

NCT06974266

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Status	RECRUITING
Phase	Not Applicable
Sponsor	Moon (Guangzhou) Biotechnology Co., Ltd.
Enrollment	60 participants

## Key Eligibility Criteria

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### Inclusion (8)

- Aged 40-60 years (inclusive), regardless of gender;
  - Patients diagnosed with hypercholesterolemia (5.2 mmol/L d TC  $\leq$ 6.2 mmol/L, or 3.4 mmol/L d LDL-C  $\leq$ 5.0 mmol/L), with or without hypertriglyceridemia (1.7 mmol/L d TG  $\leq$ 4.5 mmol/L) or mixed hyperlipidemia (defined as: 1.7 mmol/L d TG  $\leq$ 4.5 mmol/L and 5.2 mmol/L d TC  $\leq$ 6.2 mmol/L; or 1.7 mmol/L d TG  $\leq$ 4.5 mmol/L and 3.4 mmol/L d LDL-C  $\leq$ 5.0 mmol/L; or 1.7 mmol/L d TG  $\leq$ 4.5 mmol/L, 5.2 mmol/L d TC  $\leq$ 6.2 mmol/L and 3.4 mmol/L d LDL-C  $\leq$ 5.0 mmol/L);
  - Accompanied by overweight/obesity (24.0 d BMI  $\geq$ 40.0 kg/m<sup>2</sup>);
  - Have not taken any metabolic control medications (for lipid, weight, or blood glucose) within the past month;
  - Have controlled of blood lipids solely through lifestyle interventions (diet and exercise) for at least 1 month prior to the screening period;
- ... and 3 more (see full listing online)

### Exclusion (17)

- Have taken any metabolic control medications (e.g., lipid-lowering, blood glucose-regulating, or weight-loss drugs) within the past month or are currently taking such medications.
  - Patients with secondary hyperlipidemia caused by conditions such as nephrotic syndrome, liver diseases, hypothyroidism, renal failure, etc..
  - Have severe comorbidities requiring immediate treatment, including uncontrolled diabetes, hypertriglyceridemia, cerebrovascular diseases, etc., as determined by the investigator.
  - Have severe primary diseases (e.g., hepatic, renal, or hematopoietic system disorders) or psychiatric conditions.
  - Patients with a family history of genetically inherited metabolic disorders.
- ... and 12 more (see full listing online)

## Locations (1 total)

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PKUCare Luzhong Hospital, Zibo, Shandong, China