Reading Hospital
TOWER HEALTH
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Short Title	**M**etabolic **I**nterventions to **R**esolve **NA**SH with Fibrosis (**MIRNA**)
Principal Investigator	Eyob Feyssa, MD
Sub-Investigators	Andres Riera, MD Vishal Patel, MD
Study Objectives	To evaluate the drug DGAT2i compared to DGAT2i with ACCi on the treatment of nonalcoholic steatohepatitis (NASH) with liver fibrosis.

Inclusion Criteria

- Male or female participants between the ages of 18 and 75 years
- Meet two or more of the following criteria:
  - FPG ≥ 100 mg/dL (5.6 mmol/L)
  - Fasting serum HDL-C <40 mg/dL (1 mmol/L) for males and <50 mg/dL (1.3 mmol/L) for females
  - Fasting serum TG ≥150 mg/dL (1.7 mmol/L)
  - Seated BP ≥130 / 85 mm Hg
  - Waist circumference ≥40 inches (102 cm) for males and ≥35 inches (89 cm) for females
- FAST™ score ≥0.30
- ultrasound-guided liver biopsy meeting the NASH CRN definition
- BMI ≥25 kg/m^2 with upper limit of 40 kg/m^2

Exclusion Criteria

- Current significant alcohol consumption, severe hypertension, Cardiovascular event within 12 months, Recent (within 5 years) systemically administered treatments for malignancy
- Evidence of other causes of liver disease
- History of pancreatitis

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(Exclusion criteria continued…)

- Any condition possibly affecting drug absorption (eg, prior bariatric surgery, gastrectomy, ileal resection)
- Diagnosis of T2DM which requires management with >3 medications
- Dyslipidemia which requires management with >3 lipid-modifying agents

Affiliations & Sponsors Pfizer

Keywords NASH, non-alcoholic steatohepatitis, fibrosis, non-alcoholic fatty liver disease