

# AMPK-activation by Metformin in FSGS: AMP-FSGS

NCT06090227

---

<b>Status</b>	RECRUITING
<b>Phase</b>	Phase 1, Phase 2
<b>Sponsor</b>	Yale University
<b>Enrollment</b>	30 participants

## Key Eligibility Criteria

---

### Inclusion (7)

- Provision of signed and dated informed consent form
- Stated willingness to comply with all study procedures and availability for the duration of the study
- Male or female, aged greater than or equal to 18 years, but  $\leq$  80 years age at the time of signing the informed consent
- Biopsy-confirmed primary FSGS as defined by expert renal pathology at either institutions. For homogeneity of diagnoses, demonstrable segmental or global sclerosis lesions ( $\geq$ 1 glomerulus) with diffuse podocyte foot process effacement by electron microscopy ( $\geq$  50% of examined glomerular tufts), or show evidence of mesangial expansion or mesangial sclerosis, also confirmed by electron microscopy.
- Therapeutic plan by treating physician for immunomodulatory treatment using Glucocorticoids.

... and 2 more (see full listing online)

### Exclusion (18)

- Liver disease: confirmed cirrhosis liver (any stage), acute hepatitis ( $>$  2 fold increase in liver enzymes, any coagulopathy, hyperbilirubinemia, ascites or encephalopathy)
- estimated GFR  $<$  32 ml/min
- Diabetes Mellitus diagnosis at the time of biopsy or need for oral hypoglycemic agents/Insulin, or taking Metformin for other indications
- Treatment with another investigational drug or other intervention within 3 months
- Current pregnancy or desire to become pregnant during the study period

... and 13 more (see full listing online)

## Locations (2 total)

---

Yale New Haven Hospital, New Haven, Connecticut, United States  
Mount Sinai Hospital, New York, New York, United States