A Study of Auxora in Patients With Acute Pancreatitis and Accompanying SIRS

Status: Recruiting

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

All of the following must be met for a patient to be randomized into the study: 1. The diagnosis of acute pancreatitis has been established by the presence of abdominal pain consistent with acute pancreatitis together with at least 1 of the following 2 criteria: 1. Serum lipase > 3 times the upper limit of normal (ULN); 2. Characteristic findings of acute pancreatitis on abdominal imaging; 2. The diagnosis of SIRS has been established by the presence of at least two of the following four criteria: 1. Temperature < 36°C or > 38°C; 2. Heart rate > 90 beats/minute; 3. Respiratory rate >20 breaths/minute or arterial carbon dioxide tension (PaCO2) <32 mmHg; 4. White blood cell count (WBC) >12,000 mm3, or <4,000 mm3, or > 10% immature (band) forms; 3. At least one of the following criteria is also present: 1. A peripancreatic fluid collection or a pleural effusion on a contrast-enhanced computed tomography (CECT) performed in the 24 hours before Consent or after Consent and before Randomization; 2. Abdominal examination documenting either abdominal guarding or rebound tenderness; 3. Hematocrit ≥44% for men or ≥40% for women; 4. The patient is ≥ 18 years of age; 5. Lack of pancreatic necrosis, pancreatic calcifications, pancreatic pseudocysts and no evidence for previous necrosectomy or pancreatic surgery identified by CECT performed in the 24 hours before Consent or after Consent and before Randomization; 6. A female patient of childbearing potential who is sexually active with a male partner is willing to practice acceptable methods of birth control for 180 days after the last dose of study drug. A female patient must not attempt to become pregnant for 180 days; 7. A male patient who is sexually active with a female partner of childbearing potential is willing to practice acceptable methods of birth control for 180 days after the last dose of study drug. A male patient must not donate sperm for 180 days; 8. The patient is willing and able to, or has a legal authorized representative (LAR) who is willing and able to, provide informed consent to participate, and to cooperate with all aspects of the protocol.

Exclusion Criteria:

Patients with any of the following conditions or characteristics must be excluded from randomizing: 1. Expected survival <6 months; 2. Suspected presence of cholangitis in the judgment of the treating physician; 3. The patient has a known history of: 1. Organ or hematologic transplant; 2. HIV, hepatitis B, or hepatitis C infection; 3. Chronic pancreatitis; 4. Current treatment with: 1. Chemotherapy; 2. Immunosuppressive medications or immunotherapy 3. Pancreatic enzyme replacement therapy; 4. Hemodialysis or Peritoneal Dialysis; 5. The patient is known to be pregnant or is nursing; 6. The patient has participated in another study of an investigational drug or therapeutic medical device in the 30 days before randomization; 7. Allergy to eggs or known hypersensitivity to any components of study drug.

Conditions & Interventions

Interventions:
Drug: CM-4620 Injectable Emulsion or CM-4620-IE, Other: Placebo
Conditions:
Acute Pancreatitis, Systemic Inflammatory Response Syndrome

More Information

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IRB
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