Study of CM4620 to Reduce the Severity of Pancreatitis Due to Asparaginase

Status: RECRUITING

Eligibility Criteria

Sex: ALL
Age: Up to 21 years old
Healthy Volunteers: This study is NOT accepting healthy volunteers
Inclusion Criteria:

- Acute pancreatitis with elevation of amylase OR lipase ≥ 3x the upper limit of normal AND at least 1 of: abdominal pain consistent with acute pancreatitis OR imaging findings consistent with acute pancreatitis.
- Receipt of any form of asparaginase within the prior 49 days.
- Patient with acute lymphoblastic leukemia/ lymphoma age < 22 years receiving therapy with curative intent.

Exclusion Criteria:

- Prior episode of pancreatitis.
- QTc at baseline > 450 msec.
- Creatinine > 3x the upper limit of normal for age or total bilirubin >3x the upper limit for normal for age without evidence of leukemic infiltrate or hemolysis.
- Receipt of another investigational agent within the prior 7 days.
- History of allergy to eggs or known hypersensitivity to any component of CM4620.
- Positive pregnancy test or breastfeeding. Females of childbearing potential must have a negative urine or serum pregnancy test prior to enrollment. Males and females of childbearing potential must agree to use effective contraception for at least twelve months following the completion of therapy.
- Inability or unwillingness of research participant or legal guardian/representative to give written informed consent.

Conditions & Interventions

Interventions:
DRUG: CM4620
Conditions:
Acute Pancreatitis
Keywords:
Acute Pancreatitis, Asparaginase, Asparaginase Associated Pancreatitis, Acute Lymphoblastic Leukemia, Acute Lymphoblastic Lymphoma, CM4620, Children, SIRS, Systemic Inflammatory Response, Young Adults

More Information

Description:
This is a phase I/II clinical trial assessing the tolerability and efficacy of CM4620 in children and young adults with acute pancreatitis caused by asparaginase. The tolerability of CM4620 when given to patients receiving frontline chemotherapy will be determined. The effectiveness in reducing the severity of pancreatitis will be estimated. Primary Objectives To assess the safety of CM4620 administration in children and young adults with asparaginase associated pancreatitis (AAP). To profile dose-limiting toxicities and responses of the patients treated in the dose-finding phase. To estimate the efficacy of CM4620 to prevent pseudocyst or necrotizing pancreatitis in children with AAP. Secondary Objectives To determine the effect of CM4620 on the incidence of severe pancreatitis To determine the effect of CM4620 on the incidence of Systemic Inflammatory Response Syndrome (SIRS).

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