

Efficacy and Safety of Immunosuppression, Caplacizumab and Plasma Infusion Without Therapeutic Plasma Exchange in Immune-mediated Thrombotic Thrombocytopenic Purpura

NCT06291025

Status	RECRUITING
Phase	Not Applicable
Sponsor	University Hospital, Rouen
Enrollment	131 participants

Key Eligibility Criteria

Inclusion (10)

- Adult patient ≥ 18 years;
- Clinical diagnosis of iTTP based on standard clinical and laboratory criteria (French Score ≥ 2): i.e., thrombotic microangiopathy syndrome with platelet count ≤ 30 G/L and serum creatinine ≥ 200 μ ol/L; it is not necessary to have the laboratory result confirming the severe ADAMTS13 deficiency for inclusion of patient ≥ 18 (For patient with previous TTP flare, French score can be ≥ 2);
- Patient having read and understood the information letter and signed the Informed Consent Form. If the patient is unable to express his consent, the consent will be signed by his representative ((1) the trusted person, or failing that, (2) a family member, or (3) a close relative of the person concerned). In this case, consent to continue the study will subsequently be requested from the patient (article L1122-1-1 of the CSP);
- Patient affiliated with, or beneficiary of a social security (national health insurance) plan;
- For women:
... and 5 more (see full listing online)

Exclusion (16)

- Platelet count > 100 G/L before plasma treatment;
- Patients with a French score ≥ 2 (a serum creatinine level > 200 μ ol/L and/or with a platelet count > 30 G/L), in order to exclude possible cases of hemolytic uremic syndrome (except for patient with previous TTP flare, French score can be ≥ 2);
- Other known causes of cytopenias and/or organ failure including but not limited to: uncontrolled cancer, chemotherapy, transplant, drugs, HIV at AIDS stage;
- Patients with a severe neurological disorder i.e. seizure, coma, focal deficiency, trouble of consciousness;
- Pregnant women (positive result from a blood pregnancy test) or patients with an imminent project of pregnancy; breastfeeding women (due to lack of pharmacological data for caplacizumab during pregnancy and breastfeeding);
... and 11 more (see full listing online)

Locations (30 total)

Chu Amiens, Amiens, France
Chu Angers, Angers, France
Chru Besançon, Besançon, France
... and 27 more locations

<https://clinicaltrials.gov/study/NCT06291025>

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