

A Study to Learn About How Safe BAY 3389934 is, Its Suitable Dose, and How it Affects the Participants With Sepsis Induced Coagulopathy

NCT06854640

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| Status | RECRUITING |
| Phase | Phase 1 |
| Sponsor | Bayer |
| Enrollment | 36 participants |

Key Eligibility Criteria

Inclusion (6)

- Participant must be e 18 and d 80 years of age at the time of signing the informed consent.
- Participants with diagnosed sepsis according to sepsis-3 criteria. Sepsis is defined as life-threatening organ dysfunction caused by a dysregulated host response to infection.
- participants with suspected or documented origin of infection.
- Participants with coagulopathy defined by at least one of the following within 24 hours prior start of study intervention: INR e1.40, platelet count in the range of e 30,000/mm³ to \< 150,000/mm³ OR greater than 30% decrease in platelets in 24 hours without other known etiology. The platelet count after decrease should not be \< 30,000/mm³.
- Participants must be receiving treatment in an ICU.

... and 1 more (see full listing online)

Exclusion (8)

- Clinically significant active bleeding; known bleeding disorder, history of major traumatic or non-traumatic bleeding (intracranial, retroperitoneal, intraocular) or clinically significant gastrointestinal bleeding within last 6 months.
- Low platelets level or abnormal coagulation status due to any other reason than sepsis.
- Participants with indication for therapeutic dose of: anticoagulation (heparin, argatroban, vitamin K antagonists/warfarin, dabigatran, apixaban, rivaroxaban, edoxaban), oral antiplatelet agents (clopidogrel, ticagrelor, ticlopidine, prasugrel) except low dose (d100mg) acetyl salicylic acid (ASA), digoxin, metformin
- Any active malignancy
- Pregnancy or breastfeeding.

... and 3 more (see full listing online)

Locations (20 total)

UZ Antwerpen - Intensive Care, Edegem, Belgium

Centre Hospitalier Universitaire (CHU) de Liege - Domaine Universitaire du Sart Tilman - Intensive Care, Liège, Belgium

Clinique Saint-Pierre d'Ottignies - Intensive Care, Ottignies-Louvain-la-Neuve, Belgium

... and 17 more locations