Nuwiq for Perioperative Management Of Patients With Haemophilia A on Emicizumab Regular Prophylaxis Study

NCT05935358

Status	RECRUITING
Phase	Phase 4
Sponsor	Octapharma
Enrollment	28 participants

Key Eligibility Criteria

Inclusion (5)

- Severe haemophilia A (FVIII activity \[FVIII:C\] \<1%) according to medical history
- Male patients at least 12 years of age
- Previous treatment with any FVIII product(s) for at least 150 exposure days
- On regular prophylaxis with emicizumab for at least 1 month prior to a scheduled major elective surgery requiring FVIII treatment
- Freely given written informed consent of the patient, or parent/legal representative where applicable, obtained in accordance with local regulations

Exclusion (7)

- Coagulation disorder other than haemophilia A
- Present or past FVIII inhibitor (e0.6 Bethesda units \[BU\]/mL) according to medical history
- Severe liver or kidney disease (alanine aminotransferase \[ALT\] and/or aspartate aminotransferase \[AST\] levels \>5 times the upper limit of normal; or creatinine \>120 µmol/L)
- Known hypersensitivity to Nuwiq's active substance or its excipients (sucrose, sodium chloride, calcium chloride dihydrate, arginine hydrochloride, sodium citrate dihydrate, poloxamer 188)
- Already had surgery in this study

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

Locations (18 total)

UT Southwestern Medical Center, Dallas, Texas, United States
University Hospital Centre Zagreb, Zagreb, Croatia
Helsinki University Hospital, Helsinki, Finland
... and 15 more locations

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