CLARINET -- International randomized double blind study evaluating the efficacy and safety of clopidogrel 0.2 mg/kg once daily versus placebo in neonates and infants with cyanotic congenital heart disease palliated with a systemic-to-pulmonary artery shunt (e.g. modified Blalock Taussig shunt) (EFC5314)

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Synopsis:
Evaluate efficacy of 0.2 mg/kg/day of clopidogrel vs. placebo for reduction of all-cause mortality and shunt-related morbidity in neonates or infants/toddlers with cyanotic congenital heart disease palliated with a systemic-to-pulmonary artery shunt.

A Phase I bioavailability study in healthy subjects was first performed to compare a liquid formulation that was developed for use in children with the usual adult 75 mg tablet formulation. A dose-ranging study (PICOCO) in neonates and infants/toddlers at risk of thrombois (e.g., Blalock-Taussig shunt or any systemic-to-pulmonary artery shunt, Kawasaki disease, vascular stent or any pathological condition requiring antiplatelet therapy) was then performed in order to select the appropriate dose for the current trial. No safety concerns were identified during the study. The does of 0.2 mg/kg per day has bee found to be the does needed to achieve a level of ADP-induced platelet aggregation inhibition similar to the one observed in adults.