

# Model-informed Dose Optimization for Rivaroxaban in Children With Giant Coronary Artery Aneurysm After Kawasaki Disease

NCT06978439

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Status	RECRUITING
Phase	Phase 4
Sponsor	Children's Hospital of Fudan University
Enrollment	10 participants

## Key Eligibility Criteria

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### Inclusion (4)

- Giant coronary artery aneurysm(s) in any coronary artery after acute stage of Kawasaki disease. Giant coronary artery aneurysm(s) should be confirmed by two-dimensional echocardiography and meet the diagnostic criteria of Z-score  $\leq 10$  or coronary artery internal diameter  $\geq 8$ mm;
- Anticoagulant with antiplatelet drug therapy for anti-thromboprophylaxis is recommended for the next 6 months;
- Participant should be able to tolerate oral feeding, nasogastric or gastric feeding;
- Children aged 1 Month to  $< 18$  years, bodyweight  $\geq 2600$ g.

### Exclusion (13)

- Active bleeding or bleeding risk contraindicating anticoagulant therapy
- With history of venous thromboembolism or risk factors related with venous thromboembolism, like congenital heart disease, carcinoma, central venous catheter or long-term immobilization.
- Hypersensitivity or any other contraindications listed in the local labeling for the comparator treatment or experimental treatment
- An eGFR  $< 30$  mL/min/1.73 m<sup>2</sup> (For children younger than 1 year, serum creatinine results above 97.5th percentile)
- Platelet count  $< 100 \times 10^9/L$
- ... and 8 more (see full listing online)

## Locations (1 total)

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Children's Hospital of Fudan University, Shanghai, Shanghai Municipality, China