

# Efficacy and Safety of Sirolimus in Vascular Anomalies That Are Refractory to Standard Care

NCT02638389

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Status	RECRUITING
Phase	Phase 3
Sponsor	Cliniques universitaires Saint-Luc- Université Catholique de Louvain
Enrollment	250 participants

## Key Eligibility Criteria

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### Inclusion (9)

- Patients with complex vascular anomalies that are refractory to standard care such as medical treatment, surgical resection and/or sclerotherapy/embolization (ineffective or accompanied by major complications)
- Patients must have adequate medullary function: Hemoglobine  $> 10,0$  g/dl, neutrophils  $> 1500/mm^3$  and platelets  $> 100.000/mm^3$
- Patients must have the following laboratory values:
- Total serum bilirubin  $\leq 1.5$  x ULN (or totally bilirubin  $\leq 3$  x ULN with direct bilirubin  $\leq 1.5$  x ULN in patients with well documented Gilbert Syndrome)
- Serum alanine aminotransferase (ALT) and aspartate aminotransferase (AST)  $\leq 3$  x ULN (or  $< 5.0$  x ULN if hepatic metastases are present)

... and 4 more (see full listing online)

### Exclusion (8)

- Any of the following concurrent severe and/or uncontrolled medical conditions, which could compromise participation in the study or interfere with the study results:
- Impaired cardiac function or clinically significant cardiac diseases, including unstable angina pectoris, ventricular arrhythmia, valvular disease with documented compromise in cardiac function, myocardial infarction within the last 6 months, documented by persistent elevated cardiac enzymes or persistent regional wall abnormalities on assessment of LVEF function, history of documented congestive heart failure (New York Heart Association functional classification III-IV), documented cardiomyopathy, family history of congenital long or short QT, or known history of QT/QTc prolongation of Torsades de Pointes (TdP)
- Impairment of Gastro-Intestinal (GI) function or GI disease that may significantly alter the absorption of sirolimus (e.g., ulcerative diseases, uncontrolled nausea, vomiting, diarrhea e Grade 2, malabsorption syndrome, or small bowel resection)
- Known hypersensitivity to drugs or metabolites from similar classes as study treatment.
- Patient has other concurrent severe and /or uncontrolled medical condition that would, in the investigator's judgment, contraindicated participation in the clinical study (e.g. acute or chronic pancreatitis, liver cirrhosis, active chronic hepatitis, severely impaired lung function with a spirometry  $\leq 50\%$  of the normal predicted value and/or O<sub>2</sub> saturation  $\leq 88\%$  at rest, etc.)

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

## Locations (3 total)

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Cliniques Universitaires Saint-Luc, Université Catholique de Louvain Bruxelles, Brussels, Brussels Capital, Belgium  
CHU Caen, Caen, Brittany Region, France  
Universitätsklinikum Freiburg, Freiburg im Breisgau, Germany

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<https://clinicaltrials.gov/study/NCT02638389>

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