

# Efficacy of Nintedanib for Treatment of Epistaxis in Hereditary Hemorrhagic Telangiectasia (HHT) Patients

NCT04976036

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Status	RECRUITING
Phase	Phase 2
Sponsor	Dr. Romain Lazor
Enrollment	48 participants

## Key Eligibility Criteria

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### Inclusion (5)

- signed informed consent
- definite HHT disease (defined as the presence of a pathogenic mutation in one of the HHT genes, or the presence of 3 out of 4 Curaçao clinical criteria)
- age  $\geq 18$  years at the time of informed consent
- moderate to serious epistaxis defined as Epistaxis Severity Score (ESS)  $\geq 2.5$
- absence of cerebral arteriovenous malformation demonstrated by brain imaging

### Exclusion (19)

- Women who are pregnant or breastfeeding
- For women of childbearing potential (WOCBP, see Annex VII for definition), non-agreement to follow instructions for method(s) of contraception for the heterosexual couple (see Annex VII for instructions) during the treatment period and follow-up, or at least 3 months after the last dose of IMP, or if there are concerns that they will not reliably comply with the contraception requirements.
- Acute infection
- aspartate aminotransferase (AST), or alanine aminotransferase (ALT), or total bilirubin  $> 1.5x$  (or  $> 2.5x$  in patients known for Gilbert's syndrome) the upper limit of normal
- Renal clearance by Cockcroft-Gault formula  $< 30$  ml/min
- ... and 14 more (see full listing online)

## Locations (3 total)

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Lyon University Hospital, Dpt of genetics, Bron, France  
Clermont-Ferrand university hospital, Clermont-Ferrand, France  
Angiology Department, Lausanne University Hospital, Lausanne, Canton of Vaud, Switzerland