

Nintedanib in Patients With Bronchiolitis Obliterans Syndrome Following Hematopoietic Stem Cell Transplantation

NCT03805477

Status	RECRUITING
Phase	Phase 2
Sponsor	University Hospital, Basel, Switzerland
Enrollment	20 participants

Key Eligibility Criteria

Inclusion (7)

- Time interval from transplant \leq 5 years at the time of inclusion
- BOS as defined per the National Institute of Health (NIH) criteria:
- FEV1/vital capacity $<$ 0.7 or the fifth percentile of predicted.
- FEV1 $<$ 75% of predicted with \geq 10% decline over less than 2 years.
- Absence of infection in the respiratory tract, documented with investigations directed by clinical symptoms, such as chest radiographs, computed tomographic (CT) scans, or microbiologic cultures (sinus aspiration, upper respiratory tract viral screen, sputum culture, and broncho-alveolar lavage).

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

Exclusion (11)

- Known intolerance to Nintedanib or any of its component
- Pregnancy or nursing
- Serum ALT $>$ 5 x upper limit of normal (ULN) unless explained entirely by liver GvHD or total bilirubin $>$ 3x ULN unless explained entirely by liver GvHD
- Any acute pulmonary infection with viruses, bacteria or fungi within four weeks before study inclusion
- Chronic oxygen therapy; non-invasive ventilation

... and 6 more (see full listing online)

Locations (3 total)

King Faisal Specialist Hospital & Research Centre, Riyadh, Saudi Arabia
Clinic of Hematology, University Hospital Basel, Basel, Switzerland
Clinic of Respiratory Medicine, University Hospital Basel, Basel, Switzerland