

A Study to Find Out Whether BI 765423 Has an Effect on Lung Function in People With Idiopathic Pulmonary Fibrosis (IPF) With or Without Standard Treatment

NCT07036523

Status	RECRUITING
Phase	Phase 2
Sponsor	Boehringer Ingelheim
Enrollment	71 participants

Key Eligibility Criteria

Inclusion (13)

- years of age or older at the time of informed consent signature.
- Signed and dated written informed consent in accordance with International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use - Good Clinical Practice (ICH-GCP) and local legislation prior to admission to the trial.
- Male or female patients. Male patients with Woman of childbearing potential (WOCBP) sexual partners must use contraception (male condom) to avoid exposure via seminal fluid during treatment and for a specific period after last drug intake. Women can only be included if they are of non-childbearing potential, defined as meeting at least one of the below conditions:
- Permanently surgically sterilised (hysterectomy, bilateral salpingectomy and/or bilateral oophorectomy)
- Postmenopausal, defined as no menses for 12 months without an alternative medical cause. In questionable cases of postmenopausal status:
... and 8 more (see full listing online)

Exclusion (13)

- Acute exacerbation of IPF within at least 12 weeks prior to Visit 1 and/or during the screening period (investigator-determined).
- Relevant airways obstruction (pre-bronchodilator forced expiratory volume in 1 second (FEV1)/FVC \leq 0.7) at Visit 1.
- Lower respiratory tract infection requiring treatment within 4 weeks prior to Visit 1 and/or during the screening period.
- Significant PH defined by any of the following:
- Previous clinical or echocardiographic evidence of significant right heart failure according to investigator's judgement
... and 8 more (see full listing online)

Locations (50 total)

University of Alabama at Birmingham, Birmingham, Alabama, United States
Banner - University Medical Center Tucson, Tucson, Arizona, United States
University of Florida, Gainesville, Florida, United States
... and 47 more locations

<https://clinicaltrials.gov/study/NCT07036523>

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