A 52 weeks, double blind, randomized, placebo-controlled trial evaluating the effect of oral BIBF 1120, 150 mg twice daily, on Forced Vital Capacity decline , in patients with Idiopathic Pulmonary Fibrosis (IPF)

Published: 15-03-2011
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The objective of the trial is to confirm efficacy and a favorable benefit-risk ratio for BIBF 1120 in the treatment of IPF at the dose of 150 mg bid compared to placebo.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Respiratory disorders NEC
Study type	Interventional

Summary

ID

NL-OMON37976

Source
ToetsingOnline

Brief title
BIBF 1120 in IPF, phase III

Condition

- Respiratory disorders NEC

Synonym
idiopathic pulmonary fibrosis - lung fibrosis of unknown origin

Research involving
Human

Sponsors and support

Primary sponsor: Boehringer Ingelheim
Source(s) of monetary or material Support: Boehringer Ingelheim

Intervention

Keyword: BIBF 1120, Idiopathic Pulmonary Fibrosis, phase III, quality of life

Outcome measures

Primary outcome

The primary efficacy endpoint is the annual rate of decline in FVC (expressed

in mL over 52 weeks)

Secondary outcome

Change from baseline in SGRQ total score at 52 weeks (expressed in points)

time to first acute exacerbation (days)

For other secundary endpoints please refer to TP page 36 and 37.

Study description

Background summary

Idiopathic Pulmonary Fibrosis is a chronic disease of unknown aetiology that is characterized by progressive fibrotic destruction of the lung, resulting in disabling dyspnea. Up to now there is no registered treatment in The Netherlands for this fatal disease, except lung transplantation. BIBF 1120 has been studied for the treatment of IPF in large randomized, placebo controlled trials, and recently completed phase II. In phase II BIBF 1120 150 mg bid showed a positive effect on lung function compared to placebo. Also incidence of acute exacerbations was decreased and quality of life improved. BIBF 1120 is also being studied in oncology.

Study objective

The objective of the trial is to confirm efficacy and a favorable benefit-risk

ratio for BIBF 1120 in the treatment of IPF at the dose of 150 mg bid compared to placebo.

Study design

double blind, placebo controlled, randomized, 52 weeks.

Intervention

twice daily, 1 capsule BIBF 1120, 150 mg, per os. Or twice daily, 1 placebo capsule per os.

Study burden and risks

Pulmonary function testing (FEV1 en FVC): 10 x
physical examination standard: 10 x
Blood sampling:12 x
Sampling for PK: 2 x 1 sample 1 x on visit 4 and 1 x on visit 7
ECG: 5 x
Pregnancy testing (urine): 10 x
Patient questionnaires: 5 x
Dlco: 3 x.

Contacts

Public
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Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Written informed consent, Age ><= 40 years; IPF diagnosed, according to most recent ATS/ERS/JRS/ALAT IPF guideline for diagnosis and management, within 5 years; Dlco (corrected for Hb): 30%-79% predicted of normal; FVC * 50% predicted of normal.

Exclusion criteria

Laboratory parameters (AST, ALT > 1.5 x ULN; Bilirubin > 1.5 x ULN); Relevant airways obstruction (i.e. pre-bronchodilator FEV1/FVC < 0.7); Patient likely to have lung transplantation during study (being on transplantation list is acceptable for participation); Myocardial infarction within 6 months; Unstable angina within 1 month; Bleeding risk (genetic predisposition; fibrinolysis or full-dose therapeutic anticoagulation or high dose antiplatelet therapy; history of hemorrhagic CNS event within 12 months; haemoptysis or haematuria or active gastro-intestinal bleeding or ulcers or major injury or surgery within 3 months);Thrombotic risk (inherited predisposition; history of thrombotic event (including stroke and transient ischemic attacks) within 12 months; International normalised ratio (INR) > 2; prolongation of prothrombin time (PT) and partial thromboplastin time(PTT) by > 50% of institutional ULN);N-Acetyl Cystein, prednisone > 15mg/day or equivalent received within 2 weeks of visit 1; Pirfenidone, azathioprine, cyclophosphamide, cyclosporine A received within 8weeks of visit 1.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-07-2011
Enrollment:	24
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	geen
Generic name:	BIBF 1120

Ethics review

Approved WMO Date:	15-03-2011
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	16-06-2011
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	11-10-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	08-03-2012

Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	25-06-2012
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	12-11-2012
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	18-12-2012
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2010-024252-29-NL
CCMO	NL35599.100.11
Other	nog niet bekend