A phase II open label, roll over study of the long term tolerability, safety and efficacy of oral BIBF 1120 in patients with Idiopathic Pulmonary Fibrosis

Published: 02-06-2010
Last updated: 30-04-2024

to offer continuation of BIBF 1020 treatment for patients with IPF who have completed a prior clinical trial with that drug.establish the long term tolerability and safety profile of BIBF 1120 in IPF.

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

Summary

ID

NL-OMON34511

Source
ToetsingOnline

Brief title
BIBF roll over study

Condition

- Respiratory disorders NEC

Synonym
lung fibrosis of unknown origin

Research involving
Human

Sponsors and support

Primary sponsor: Boehringer Ingelheim

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

Intervention

Keyword: BIBF 1120, Idiopathic lung fibrosis, roll over study

Outcome measures

Primary outcome

Forced Vital Capacity decline (slope of decline between study entry and end of

treatment)

Secondary outcome

Overall survival, progression free survival, yearly decline in DLco and IPF

exacerbations

Study description

Background summary

Idiopathic Pulmonary Fibrosis is a chronic disease of unknown aetiology that is characterized by progressive fibrotic destruction of the lung. Currently there is no drug registered for this fatal disease other than lung transplantation. BIBF1120 is currently ideveloped to treat IPF in randomized, placebo controlled trials. Patients who may have experienced benefit from the drug in the randomized parent trial will be given the possibility to continue the treatment after the parent trial is completed.

Study objective

to offer continuation of BIBF 1020 treatment for patients with IPF who have completed a prior clinical trial with that drug.
establish the long term tolerability and safety profile of BIBF 1120 in IPF.

Study design

open label, roll over

Study burden and risks

Before entry in study 1199.35, patients have already been treated with BIBF 1120. Therefore, the possible side effects are made known to them. Liver function is closely monitored at in between visits. Blood sampling is done by qualified medical personnel. Currently there is no cure for IPF. The lung function tests are part of standard practice for this group of patients.

Contacts

Public
Boehringer Ingelheim

Comeniusstraat 6
1817 MS Alkmaar
NL
Scientific
Boehringer Ingelheim

Comeniusstraat 6
1817 MS Alkmaar
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. patients with primary diagnosis of IPF, who are willing to continue trial medication
2. written informed consent signed prior to entry into the study, in accordance with ICH-GCP
3. completion of 1199.30 study and still under treatment (i.e. not discontinued in parent trial)

Exclusion criteria

1. any disease that may put the patient at risk when participating in this trial
2. participation in another experimental trial in the last 8 weeks
3. women of breast feeding or of child bearing potential, not using a highly effective method of birth control for at least one month prior to inclusion and at least 10 weeks after end of active therapy.
4. sexually active males not comitting to using condoms during the course of the study and at least 10 weeeks after the end of active therapy.
5. patients who require full dose anticoagulation or antiplatelets
6. known or suspected active alcohol or drug abuse
7. patients not compliant in parent trial, with trial medication or visits

Study design

Design

Study phase:	2
Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-09-2010
Enrollment:	7
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO Date:	02-06-2010
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	24-08-2010
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	20-09-2010
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	28-10-2010
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	24-12-2010
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	24-01-2011
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:	13-04-2012
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	16-01-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	18-01-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	13-03-2014
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	18-03-2014
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	06-08-2014
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	08-08-2014
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	07-08-2015
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United

	(Nieuwegein)
Approved WMO Date:	14-08-2015
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	EUCTR2009-013788-21-NL
CCMO	NL32265.100.10