A prospective, multicenter, randomised, open-label, active controlled, 2 parallel groups, phase 3 study to compare the efficay and safety of masitinib to sunitinib in patients with gastrointestinal stromal tumor after progression with imitinib

Published: 18-10-2012
Last updated: 16-11-2024

The objective is to compare the efficacy and safety of masitinib 12 mg/kg/day to sinutinib 50 mg/day

Ethical review	Approved WMO
Status	Completed
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Interventional

Summary

ID

NL-OMON44774

Source
ToetsingOnline

Brief title
AB11002

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC
- Gastrointestinal neoplasms malignant and unspecified

Synonym
gastro-intestinal stomal tumor (GIST)

Research involving
Human

Sponsors and support

Primary sponsor: AB Science
Source(s) of monetary or material Support: Industry

Intervention

Keyword: (GIST), gastrointestinal stromal cancer, masitinib, tyrosine kinase inhibitor

Outcome measures

Primary outcome

Overall survival

Secondary outcome

- time to treatment failure,

- overall progression free survival rate at weeks 8, 16, 24 and then every 12

weeks

- survival rate at weeks 8, 16, 24 and the every 12 weeks

- overall time to progression

- time to progression rate at weeks 8, 16, 24 and then every 12 weeks

- best response

- best response rate

- objective response

- objective response rate

- disease control

disease control rate at weeks 8, 16, 24 and then every 12 weeks

Study description

Background summary

protocol version 8, 15 december 2014: p37 - p62

Study objective

The objective is to compare the efficacy and safety of masitinib 12 mg/kg/day to sinutinib 50 mg/day

Study design

prospective, multicenter, randomised, open-label, active-controlled, two-parallel groups, phase 3 study.

Intervention

- 175 patients will be treated with masitinib 12 mg/kg/day
- 175 patients will be treated with sinutinib 50 mg/day

Study burden and risks

Not applicable

Contacts

Public
AB Science

Alfons Smetsplein 3H1
Leuven 3000
BE
Scientific
AB Science

Alfons Smetsplein 3H1
Leuven 3000
BE

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. patient with histological proven metastatic GIST (gastro-intestinal stromal cancer) or non-operable locally advanced GIST;
2. patient with measurable tumor lesions with longest diameter >=20 mm using conventional techniques or >= 10 mm with spiral CT scan according to Recist 1.1;
3. patient with C-kit (CD117) positive tuimour detected immunohistochemically;
4. patient after progression with imatinib up to 800mg;
5. patient with ECOG <=2;
6.Patient with adequate organ functions;
7. patient with life expectancy >3 months;
8. male or female >18 years;
9. patient with a BMI > 18 kg/m2 and weightening at least 40 kg;

Exclusion criteria

1. patient treated for a cancer other vthan GIST within 5 years before enrolmentwith the exception of basal cell carcinoma or cervical cancer in situ;
2. patient with active CNS metastasis or with history of CNS mtastasis;
3. patient with certain cardiac disorder;
4.patient with history of poor compliance or history of drug/alcohol abuse or excessive alcohol beverage consumption;
5. pregnant or nursing female

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	10-10-2013
Enrollment:	30
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	masitinib
Generic name:	masitinib

Ethics review

Approved WMO Date:	18-10-2012
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	07-06-2013
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	11-07-2013

Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	10-10-2013
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	26-11-2013
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	18-12-2013
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	03-02-2014
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	19-02-2015
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	20-02-2015
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	19-07-2016
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO Date:	03-03-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	08-03-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	04-09-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	07-06-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	14-06-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	18-10-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	06-11-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
Other	0069-0550-38
EudraCT	EUCTR2011-001790-41-NL
CCMO	NL41704.078.12