Study 200170: A Rollover Study to Provide Continued Treatment with Eltrombopag

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To provide continuing treatment with eltrombopag for subjects who are currently participating in a GSK sponsored investigational study of eltrombopag (parent study) and to collect long term safety data.

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

Summary

ID

NL-OMON44543

Source
ToetsingOnline

Brief title
TRC200170

Condition

- Haematological disorders NEC

Synonym
thrombocytopenia; decrease number of platelets

Research involving
Human

Sponsors and support

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

Intervention

Keyword: AML, eltrombopag, MDS, thrombocytopenia

Outcome measures

Primary outcome

Adverse effects.

Secondary outcome

None.

Study description

Background summary

Eltrombopag is an orally bioavailable, small molecule thrombopoietin receptor agonist that is being studied in patients with medical disorders associated with thrombocytopenia. It has been approved for the treatment of chronic idiopathic thrombocytopenic purpura (ITP) in adults (after splenectomy or if refractory for other treatments). ITP is a disease a low number of platelets (<150 Gi/L). In myelodysplastic syndrome (MDS) and acute myeloid leukemia (AML), megakaryopoiesis can be impaired in both a quantitative (lack of megakaryocytes), and qualitative way (increased apoptosis in megakaryocytes from patients with MDS). Interestingly, increased apoptosis of megakaryocytes has also been observed in ITP. Based on the pathophysiology of thrombocytopenia in MDS and AML and based on eltrombopag*s known mechanism of action, it is very likely that eltrombopag will be effective in patients with MDS and AML.
This study is a follow-up study for patients with ITP, MDS and AML who have completed one of the core studies with eltrombopag in ITP, MDS en AML. The main aim is to provide the option to these patients to continue the use of eltrombopag. In Holland only MDS and AML patients from the ASPIRE study (TRC114968) will participate in this follow-up study.

Study objective

To provide continuing treatment with eltrombopag for subjects who are currently participating in a GSK sponsored investigational study of eltrombopag (parent study) and to collect long term safety data.

Study design

Phase IV uncontrolled open-label study.
All patients will be treated with eltrombopag. The starting dose will be the final dose used in the core study. Thereafter dose adjustments may be performed.
The study may remain open until commercial supply of eltrombopag is available to patients with the same disease as you, or another way for you to receive eltrombopag becomes available or until GSK stops the development of eltrombopag.
Standard of care therapies will be continued.
Approx. 100 patients.

Intervention

Treatment with eltrombopag.

Study burden and risks

Risk: Adverse effects of study medication.
Burden: Treatment every 1-2 weeks or 1-2 months depending on platelet counts.
Each visit: physical examination, blood draw (10-15 ml).
At study start: ECG and pregnancy test (if relevant).

Contacts

Public
GlaxoSmithKline

Huis ter Heideweg 62
Zeist 3705 LZ
NL
Scientific
GlaxoSmithKline

Huis ter Heideweg 62
Zeist 3705 LZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

* The subject is participating in a GSK sponsored investigational study of eltrombopag (parent study) within the past 28 days and is receiving clinical benefit without unacceptable toxicity as determined by the investigator.
* Female participants and female partners of male participants of child-bearing potential: subject must not be sexually active or is practicing an acceptable method of contraception.

Exclusion criteria

* Permanent discontinuation of eltrombopag in the parent study based upon the study treatment discontinuation or study withdrawal criteria from the parent study.
Subjects who permanently discontinued treatment because they completed all study related treatments remain eligible.
* Pregnancy and breast feeding. Inadequate contraception, if relevant.

Study design

Design

Study phase:	4
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-05-2014

Enrollment:	2
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Revolade
Generic name:	eltrombopag
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	19-03-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-05-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-06-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	09-02-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-02-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-11-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	clinicaltrials.gov; registratienummer n.n.b.
EudraCT	EUCTR2013-001371-20-NL
CCMO	NL48025.029.14