An Open Label Study of AMG 531 in Severely Refractory Thrombocytopenic Subjects with Immune (Idiopathic) Thrombocytopenic Purpura (ITP)

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Primary:To demonstrate the safety of AMG 531 in severely refractory thrombocytopenic subjects with ITPSecondary:To monitor hematological responses to AMG 531To provide open-label use of AMG 531, and to investigate its utility in severely refractory…

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

Summary

ID

NL-OMON31615

Source
ToetsingOnline

Brief title
Thrombocytopenia in subjects with ITP

Condition

- Platelet disorders

Synonym
Immune (idiopathic) Thrombocytopenic Purpura

Research involving
Human

Sponsors and support

Primary sponsor: Amgen

Source(s) of monetary or material Support: Amgen

Intervention

Keyword: AMG 531, Immune Thrombocytopenic Purpura, Phase 2

Outcome measures

Primary outcome

The incidence of adverse events, including clinically significant changes in

laboratory values and incidence of antibody formation.

Secondary outcome

The incidence of platelet response. A platelet response is defined as a

doubling of baseline platelet count and a platelet count equal or bigger then

50 x 10-9 / L.

Study description

Background summary

The 20040209 study has been conducted as an individual patient protocol in the US since 2004. Currently, we have 38 patients enrolled in the study at 23 sites. With increasing requests from health care professionals for AMG 531 for the treatment of severely refractory ITP subjects, the protocol has been amended so that it is scalable for other regions (Europe and Australia). The protocol has been designed to provide open label AMG 531 to severely thrombocytopenic patients with ITP who are refractory to other treatments, and who do not qualify for ongoing AMG 531 ITP studies. The protocol will therefore increase our understanding of AMG 531 in ITP subjects with severely refractory thrombocytopenia.

Study objective

Primary:
To demonstrate the safety of AMG 531 in severely refractory thrombocytopenic subjects with ITP

Secondary:

To monitor hematological responses to AMG 531
To provide open-label use of AMG 531, and to investigate its utility in severely refractory thrombocytopenic subjects with ITP who do not qualify for any ongoing ITP studies

Study design

Study design:
This protocol will provide open label AMG 531 to severely thrombocytopenic subjects with ITP who are refractory to other treatments, and who do not qualify for ongoing AMG 531 ITP studies. This protocol will therefore expand our understanding of AMG 531 in ITP subjects with severely refractory thrombocytopenia. All subjects will enter this study at a starting dose of 3 micrograms per kilogram. AMG 531 will be administered by subcutaneous injection once per week. Dose adjustment will be based on platelet counts, and will be allowed throughout the duration of the study (see the dose adjustment table in Section 6.2). Rescue therapy is allowed at any time during the study. Reductions in concurrent IT therapies may occur at any time when platelet counts are greater than 50 x 109/L. An end of study visit must be completed for all subjects that complete or discontinue the study early.

Intervention

AMG 531 will be administered at a starting dose of 3 microgram per kilogram. Dose adjustment will be governed by the following rules:

Platelet counts (x10-9/ L) less then 200: Dose may be adjusted (increase or decreased) weekly at the investigator*s decision
Bigger or equal 200 -450: Maintain current dose, or decrease weekly at the investigators decision
Bigger than 450: Withhold the next scheduled dose. Dose will be reduced on the next scheduled dosing day that the l\platelet count is less then 200 x 10-9 / liter

Study burden and risks

Not applicable.

Contacts

Public
Amgen

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NL
Scientific
Amgen

Minervum 7061
4800DH Breda
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Inclusion Criteria:
* Subject is * 18 years of age
* Subject has a diagnosis of immune (idiopathic) thrombocytopenic purpura per the American Society of Hematology guidelines (see Appendix B)
* Subject had a bone marrow biopsy and aspirate consistent with ITP conducted within 2 years of screening
* Subject*s platelet count is * 20 x109/L or the subject is experiencing bleeding that is uncontrolled with conventional therapies
* Subject has failed at least 3 conventional therapies for ITP and, in the opinion of the treating physician, is unlikely to respond to other available therapies
* If a subject has a history of atrial fibrillation, subject is currently receiving anti-coagulation medication
* Subject is willing and able to provide written informed consent

Exclusion criteria

Exclusion Criteria:
* Subject has a history of arterial thrombosis (eg, cerebrovascular accident, transient ischemic attack, myocardial infarction)
* Subject has a history of venous thrombosis (eg, deep vein thrombosis, pulmonary embolism)
* Subject has a history of human immunodeficiency virus, hepatitis B virus, hepatitis C virus, or any other systemic infectious disease known to cause severe thrombocytopenia
* Subject has a history of disseminated intravascular coagulation or underlying hypercoaguable state
* Subject has a history of any of the following autoimmune disorders: systemic lupus erythematosis, Evans Syndrome, autoimmune neutropenia, lupus anticoagulant or antiphospholipid antibody syndrome, or active vasculitis
* Subject has a history of microangiopathic hemolytic anemia (ie, hemolytic uremic syndrome, thrombotic thrombocytopenic purpura)
* Subject has active lymphoproliferative or immunoproliferative (monoclonal gammopathy of undeterimined significance, multiple myeloma) disorder or leukemia
* Subject has a history of a myeloproliferative disorder (eg, myelofibrosis, chronic myelogenous leukemia)
* Subject has myelodysplastic syndrome
* Subject with a history of exposure to mutagenic chemotherapy has either dysplastic cytological findings or abnormal cytogenetics on bone marrow study
* Subject has a history of paroxysmal nocturnal hemoglobinuria
* Subject has participated in any study evaluating PEGrHuMGDF, recombinant human thrombopoietin (rHuTPO), or related platelet product
* Subject has a known hypersensitivity to any recombinant E coli-derived product
* Subject has received any therapeutic drug or device that is not approved by the local regulatory health agency for any indication within 4 weeks of screening
* Subject is of reproductive potential and is not using

adequate contraceptive precautions, in the judgment of the investigator
* Subject is pregnant or breast feeding
* Investigator has concerns regarding the subject*s ability to comply with the protocol procedures

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-05-2008
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	18-02-2008
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	28-02-2008
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)

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Approved WMO Date:	05-08-2008
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO Date:	16-10-2008
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO Date:	13-01-2009
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO Date:	15-01-2009
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO Date:	12-03-2009
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO Date:	06-04-2009
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)

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Approved WMO Date:	07-07-2009
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO Date:	21-07-2009
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO Date:	05-10-2009
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO Date:	07-10-2009
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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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	EUCTR2007-000638-37-NL
CCMO	NL20473.098.07
Other	nog niet bekend