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A phase Ib/IIa clinical trial to investigate the safety and efficacy of recombinant human soluble Fc-gamma receptor IIb (SM101) for intravenous application in the treatment of patients with chronic adult idiopathic thrombocytopenic purpura (ITP)

Submission date
04/02/2010

Registration date
18/05/2010

Last Edited
19/04/2011

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Haematological Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mr Sascha Tillmanns

Contact details
Am Klopferspitz 19
Martinsried/ Munich
Germany
82152

Additional identifiers

Protocol serial number
SM101-201-itp-09

Study information

Scientific Title
A randomised, multicentre, double-blind, placebo-controlled, single/multiple dose escalation phase Ib/IIa clinical trial to investigate the safety and efficacy of recombinant human soluble Fc-gamma receptor IIb (SM101) for intravenous application in the treatment of patients with chronic adult idiopathic thrombocytopenic purpura (ITP)

Study objectives
The primary objective of this trial is to evaluate the safety and tolerability of intravenously administered SM101 at various dose levels in a single/multiple dosing manner in subjects with chronic idiopathic thrombocytopenic purpura (ITP).

The secondary objective of this trial is to evaluate the efficacy, e.g. platelet count, pharmacokinetic and immunological parameters of intravenous (iv) administered SM101.

As of 19/04/2011 the anticipated end date for this trial has been extended from 31/01/2011 to 26/10/2012.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Russia: Ethics Committee of the Federal Service on Surveillance in Health Care and Social Development approved on the 21st October 2009
2. Belgium: K.U. LEUVEN Hospitals Medical Ethics Committee approved on the 6th January 2010
3. Poland: Komisja Bioetyczna Slaskiego Uniwersytetu Medycznego w Katowicach approved on the 5th January 2010
4. Germany: Ethik-Kommission des Fachbereichs Medizin der Justus-Liebig Universitaet Giessen approved on the 14th January 2010
5. Ukraine: Ministry of Health of Ukraine, Central Ethics Committee approved on the 1st June 2010

Study design
Randomised multicentre double blind placebo-controlled dose escalation and extension trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Chronic adult idiopathic thrombocytopenic purpura

Interventions
SM101 is a recombinant, soluble, non-glycosylated version of the human Fc- receptor Fc-RIIb.

This trial consists of a dose escalation and an extension part. In the dose escalation part, each dose group consists of 4 verum and 2 placebo patients who will receive verum or placebo as a single administration. The patients will be followed up for 4 weeks and will then continue with 4 weekly injections of verum or placebo. With an additional follow-up period of 12 weeks, the patients of one dose group complete their study participation.

Extension part:
The extension part will be conducted with an additional 15 newly recruited patients (10 verum, 5 placebo) in a parallel fashion and the subjects will receive a total of 4 IMP administrations. The subjects will then be followed for 3 months.

Intervention Type
Drug

Phase
Phase I/II

Drug/device/biological/vaccine name(s)
Recombinant human soluble Fc-gamma receptor IIb (SM101)

Primary outcome(s)
Incidence, severity, causality and seriousness of adverse events (AEs), laboratory results and AEs of special interest including bleeding events. AEs will be graded using the Common Terminology Criteria for Adverse Events (CTCAE), version 3.0.

Adverse Events will be recorded at an ongoing basis at every visit performed throughout the study (dose escalation part: screening, week 1, 2, 3, 4, 5, 6, 7, 8, 10, 12, 14, 16, 18, 20; extension part: screening, week 1, 2, 3, 4, 5, 8, 12, 16).

Key secondary outcome(s))
1. Proportion of subjects with a substantial platelet response defined as:
1.1. Platelet count greater than or equal to 30,000/µL from at least two blood samples, and
1.2. At least two-fold increase of platelet count from baseline values from at least two blood samples
2. The following will be defined as efficacy end-points:
2.1. Mean time to reach substantial platelet response
2.2. Mean duration of platelet count greater than or equal to 30,000/µL
2.3. Mean time to reach first platelet count of greater than or equal to 30,000/µL
2.4. Proportion of subjects requiring rescue medication until end of study
2.5. Proportion of subjects with World Health Organisation (WHO) bleeding events grade 2 (mild blood loss) or higher until end of study
2.6. Immunological markers and IMP PK parameters

The platelet count will be determined at every visit performed throughout the study (dose escalation part: screening, week 1, 2, 3, 4, 5, 6, 7, 8, 10, 12, 14, 16, 18, 20; extension part: screening, week 1, 2, 3, 4, 5, 8, 12, 16). On treatment days (escalation part: days 1, 36, 43, 50 and 47; extension part: days 1, 8, 15 and 22) the platelet count will be measured 0.5 hours prior to dosing and 2, 4, 12, 24 and 48 hours after start of IMP administration.

Completion date
26/10/2012

Eligibility

Key inclusion criteria

1. Written informed consent prior to any study related procedure
2. Male or female subjects aged 18 to 75 years, with or without splenectomy
3. Diagnosis of chronic idiopathic thrombocytopenic purpura (ITP) based on subject's history, physical examination, blood count and blood film examination according to the British Society for Haematology (BSH) and American Society of Hematology (ASH) guidelines for at least 6 months
4. Subject has previously received at least one ITP therapy
5. Platelet count less than 30,000/µL from at least two measurements
6. Subjects greater than 60 years of age must have had a documented history of chronic ITP with a bone marrow report to confirm the diagnosis

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Female subjects who are nursing or pregnant, who may be pregnant, or who contemplate pregnancy during the study period
2. Secondary thrombocytopenia
3. Subject received rituximab or any other B-cell depleting agent within 24 months preceding the first dose of investigational medical product (IMP)
4. All other previously completed ITP treatment must achieve at least 5 times their terminal half-life prior to first administration of IMP
5. Subject receives concomitant ITP medication other than corticosteroids, except rescue medication during the clinical trial
6. Splenectomy within 4 weeks prior to screening
7. History of or current alcohol or drug abuse
8. Any condition which in the judgment of the Investigator would place the subject at undue risk or interfere with the results of the study

Date of first enrolment
07/04/2010

Date of final enrolment
26/10/2012

Locations

Countries of recruitment
Belgium

Germany

Poland

Russian Federation

Ukraine

Study participating centre
Am Klopferspitz 19
Martinsried/ Munich
Germany
82152

Sponsor information

Organisation
SuppreMol GmbH (Germany)

ROR
https://ror.org/05jgtkc28

Funder(s)

Funder type
Industry

Funder Name
SuppreMol GmbH (Germany)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration