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SM101 In systemic lupus erythematosus patients with or without a history of lupus nephritis

Submission date
30/06/2011

Recruitment status
No longer recruiting

Registration date
25/08/2011

Overall study status
Completed

Last Edited
14/12/2017

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
In autoimmune diseases such as systemic lupus erythematosus (SLE), the immune system has lost the ability to discriminate between body-own ('self') and foreign proteins. In consequence, antibodies are generated to attack 'self'-proteins and form immune complexes which continuously activate the immune system through binding to specific immune cells in the body. As a result, the activated immune system can lead to severe organ damage, including the kidney. This study investigates a new treatment for preventing and/ or ameliorating SLE in patients with or without a history of lupus nephritis ((prolonged inflammation of kidneys). Previous investigations in SLE animal studies suggest that the drug SM101 competes with the immune complex binding and has the potential to prevent organ damage caused by the activated immune system. The aim of this study is to investigate the safety and efficacy of SM101 in the treatment of SLE patients with or without a history of lupus nephritis and a SELENA-SLEDAI score of ≥ 6.

Who can participate?
SLE patients with or without a history of lupus nephritis and a SELENA-SLEDAI score of ≥ 6.

What does the study involve?
The study includes 10 visits for non-pharmacokinetic (PK) patients and 13 visits for PK patients. There is a 3 weeks screening period, a 4 weeks treatment and a 5 months follow-up period.

What are the possible benefits and risks of participating?
Previous studies suggest that SM101 appears to be generally well tolerated and safe. However, some patients may experience some adverse reactions which have not been reported so far. The side effects may be a minor inconvenience or could be severe. Patients will be watched closely for any side effects, and the drug will be stopped if serious side effects develop.

Where is the study run from?
Thirty clinical trial sites for the SMILE study are located in Australia, Belgium, Czech Republic, France, Germany, Italy, Netherlands, Poland, Spain and UK.

When is the study starting and how long is it expected to run for?
The first enrolment of patients is planned for August 2011 with a recruitment period of 14 months until October 2012.

Who is funding the study?
SuppreMol GmbH (Germany)

Who is the main contact?
Sascha Tillmanns, Medical Director, SuppreMol GmbH
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
SM101-201-sle-10

Study information

Scientific Title
Phase IIa, 2:2:1 randomised, double-blind, placebo-controlled, parallel group, multi-centre clinical trial to investigate the safety, efficacy and pharmacokinetics of recombinant human soluble Fc-gamma receptor IIb (SM101) for intravenous application in the treatment of systemic lupus erythematosus (SLE) patients with or without a history of lupus nephritis

Acronym
SMILE

Study objectives
The human soluble Fcγ receptor SM101 competes with the binding of systemic lupus erythematosus (SLE)-specific immune complexes to effector cells and therefore interrupts the immunological cascade leading to inflammation and organ damage.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval pending as of 30/06/2011

Study design
Phase IIa 2:2:1 randomised double-blind placebo-controlled parallel group multi-centre proof-of-concept clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Systemic lupus erythematosus patients with or without a history of lupus nephritis

Interventions
Three treatment arms, two interventions groups and a placebo in parallel fashion:
1. Intervention group 1: 6 mg/kg/week SM101 for 4 weeks
2. Intervention group 2: 12 mg/kg/week SM101 for 4 weeks
3. Placebo

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
SM101

Primary outcome measure

Incidence of adverse events (AEs) during the study period according to Common Terminology Criteria for Adverse Events (CTCAE)

Secondary outcome measures
1. Physical examination (screening)
2. Vital signs (screening, treatment, follow-up)
3. Body temperature (screening, treatment, follow-up)
4. Body weight (screening, treatment)
5. Electrocardiogram (ECG) (screening, treatment, follow-up)
6. Safety laboratory assessments (screening, treatment, follow-up)
7. Anti-drug antibody (ADA) (treatment, follow-up)
8. AE recording (continuously)
9. Overall and renal disease score assessments, proteinuria, urine sediment, glomerular filtration rate (GFR), biological markers, anti-double-stranded DNA (dsDNA), anti-C1q, C3, C4, urinary neutrophil gelatinase-associated lipocalin (uNGAL) (continuously)
10. Use of rescue medication (all during screening, treatment, follow-up)

Overall study start date
01/08/2011

Completion date
01/07/2013

Eligibility

Key inclusion criteria
1. Patient has provided written informed consent prior to any study-related procedure
2. Male or female adult patients aged 18 years or older
3. Diagnosis of SLE meeting at least four revised main classification criteria of the American College of Rheumatology (ACR) with or without a history of glomerulonephritis
4. Clinically active patients with a SLE Disease Activity Index (SELENA-SLEDAI) score of ≥ 6
5. Patients with a current serological active status (anti-dsDNA or C3)
6. Concurrent maintenance immunosuppressant SLE treatment (if any) with prednisone alone or in combination with either azathioprine or mycophenolate mofetil
7. Adequate liver function

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
50 patients

Key exclusion criteria
1. Patient is intended to receive immunosuppressive SLE treatment other than listed in the inclusion criteria
2. Patients with proteinuria > 3.5 g/day at baseline or glomerular filtration rate (GFR) < 60 mL /min/1.73 m2
3. Patients with active SLE neurological disorders
4. Patients with an acute British Isles Lupus Assessment Group (BILAG) score defined as >= 1 BILAG A score or >= 2 BILAG B scores
5. History of class VI glomerulonephritis
6. Patients with non-lupus related renal disease such as microthrombotic disease associated with antiphospholipid syndrome
7. Patients with other acute infections
8. Patient received any B cell depleting therapy

Date of first enrolment
01/08/2011

Date of final enrolment
01/10/2012

Locations

Countries of recruitment
Australia

Belgium

Czech Republic

France

Germany

Italy

Poland

Spain

United Kingdom

Study participating centre
SuppreMol GmbH
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Sponsor information

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Sponsor type
Industry

ROR
https://ror.org/05jgtkc28

Funder(s)

Funder type
Industry

Funder Name
SuppreMol GmbH (Germany)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration