An exploratory, open-label, single centre, phase II, proof of concept study of gevokizumab treatment in patients with Schnitzler syndrome.

Published: 15-07-2013
Last updated: 22-04-2024

The objective of this study is to explore the efficacy and safety of gevokizumab in patients with Schnitzler syndrome.

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

Summary

ID

NL-OMON40255

Source
ToetsingOnline

Brief title
open label study with gevokizumab in patients with Schnitzler syndrome.

Condition

- Autoimmune disorders

Synonym
schnitzler syndrome

Research involving
Human

Sponsors and support

Primary sponsor: Servier R&D Benelux
Source(s) of monetary or material Support: Institut de Recherches Internationales

Servier

Intervention

Keyword: schnitzler syndrome

Outcome measures

Primary outcome

Exploratory descriptive endpoints on efficacy and safety.

Secondary outcome

not applicable

Study description

Background summary

The purpose of this study is to assess the efficacy and safety of a new drug called gevokizumab in treating Schnitzler syndrome. The Schnitzler syndrome is a rare chronic inflammatory disease characterised by recurrent urticarial rash of the skin, recurrent fever, bone or arthritis pain and high levels of certain proteins in the blood called immunoglobulins. The present study will assess if the tested drug can improve the Schnitzler syndrome by reducing the inflammatory agents involved in the development of the disease.

Study objective

The objective of this study is to explore the efficacy and safety of gevokizumab in patients with Schnitzler syndrome.

Study design

This is a phase II exploratory, single-centre, open-label, proof of concept study .

Intervention

Subcutaneous injection of gevokizumab.

Study burden and risks

cfr E2 and E9

Contacts

Public
Servier R&D Benelux

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BE
Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Male or female, aged >= 18 years
- Weight >= 45 kg and <= 125 kg
- For subjects with reproductive potential, a willingness to use highly effective contraceptive measures, and for female subjects a negative serum pregnancy test
- Probable or definite Schnitzler syndrome according to Strasbourg criteria.

Exclusion criteria

- Differential diagnoses other than Schnitzler syndrome,
- Any prior treatment with systemic alkylating agents within the previous 6 months prior to selection,
- Active TB disease,
- History of severe allergic or anaphylactic reactions to monoclonal antibodies,
- History of malignancy within 5 years prior to selection,
- Known immunodeficiency,
- Infectious disease,
- Any live (attenuated) vaccine within 3 months prior to selection,
- Pregnancy, breastfeeding or possibility to become pregnant during the study

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):	16-12-2013
Enrollment:	5
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	niet van toepassing
Generic name:	gevokizumab

Ethics review

Approved WMO Date:	15-07-2013
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	10-10-2013
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	31-07-2014
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	15-09-2014
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	14-11-2014
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	27-11-2014
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	25-02-2015
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	06-03-2015
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	EU clinical trials register (https : // www.clinicaltrialsregister.eu)via eudract form
EudraCT	EUCTR2013-002562-39-NL
CCMO	NL45331.091.13