Pharmacokinetic evaluation of long-term Xolair-therapy in severe asthma patients

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON25198

Source
Nationaal Trial Register

Brief title
PHLOX

Health condition

Allergic Asthma

Sponsors and support

Primary sponsor: Medical Centre Leeuwarden
Source(s) of monetary or material Support: MCL Academy Science-committee

Intervention

Outcome measures

Primary outcome

The percentage of patients with a ratio omalizumab trough-level to baseline IgE larger than 15:1

Secondary outcome

Association of the ratio omalizumab trough-level to baseline IgE and patients yearn for the next gift
Association of the ratio omalizumab trough-level to baseline IgE and asthma-related outcomes (ACQ, AQLQ, FEV1, NO)

Study description

Background summary

Omalizumab has been used in the treatment of severe allergic asthma for several years. Early trials found that adequate suppression of IgE was achieved when omalizumab was in excess over IgE 15:1. It remains unknown what this ratio is in patients treated for more than a year. Furthermore, some patients are able to extend their dose-interval, while some patients indicate that they yearn for their next omalizumab gift. In this trial the ratio between trough omalizumab-level and baseline IgE will be examined. The patients yearn for the next gift and the correlation with the ratio between trough omalizumab-level and baseline IgE will be examined.

Study objective

Our hypothesis is that the ratio omalizumab trough-level to baseline IgE differs from the 15:1 ratio, which was found to induce adequate asthma-suppression in early trials.
The patients yearn for the next gift may be associated with an inadequate ratio.

Study design

Data will be collected during the 6-month evaluation

Intervention

N/A

Contacts

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Eligibility criteria

Inclusion criteria

Severe asthma patients, receiving more than 12 months of omalizumab therapy, >18 months old, able to sign informed consent.

Exclusion criteria

None

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	N/A: single arm study
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-06-2019
Enrollment:	30
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Plan description
N/A

Ethics review

Positive opinion

Date:	06-06-2019
Application type:	First submission

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
NTR-new	NL7794
Other	RTPO Leeuwarden : nWMO 375

Study results

Summary results
N/A