A phase II, randomized, double-blind, placebo controlled, parallel design, dose ranging, multi-center trial of four levels of exposure of QGE031 s.c. for 16 weeks in subjects aged 18-50 years with peanut allergy (CQGE031A2208)

Published: 04-08-2011
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Primary: To characterize the QGE031 dose response relationship for the increase in the threshold dose of peanut protein that induces objective hypersensitivity reactions after treatment.Secondary (only key parameters): The percentage of patients...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Allergic conditions
Study type	Interventional

Summary

ID

NL-OMON37823

Source
ToetsingOnline

Brief title
CQGE031A2208

Condition

- Allergic conditions

Synonym
peanut allergy

Research involving

Human

Sponsors and support

Primary sponsor: Novartis
Source(s) of monetary or material Support: Novartis-Pharma BV

Intervention

Keyword: allergy, challenge, peanut, QGE031

Outcome measures

Primary outcome

QGE031 dose response relationship for the increase in the threshold dose of peanut protein that induces objective hypersensitivity reactions after treatment.

Secondary outcome

The percentage of patients that experienced an increase from baseline to the end of treatment period in the threshold dose of at least 2 steps (or 10 fold) increase in peanut dose; safety and tolerability.

Study description

Background summary

With peanut allergy only a small quantity of the allergen may result in serious and potentially life-threatening allergic reactions. The pathology is IgE mediated. In the US peanut allergy is the most important cause of fatal allergic reactions. The incidence seems to increase (from 0,4% in 1997 to 1,4% in 2008).
The only available therapy is strict abstinence of the consumption of peanuts and peanut protein containing substances. The risk of accidental use is present, also because of the widespread use of peanut by the food industry and problems with accurate labeling. According to a 5 year study 50% of participants 58% of subjects experienced adverse reactions from accidental peanut exposure despite best efforts at allergen avoidance. In children the

problem is more explicit than in adults.
QGE031 is a humanized monoclonal antibody directed against human IgE and is a highly potent inhibitor of human IgE binding to the IgE receptor. The level of IgE onderdrukking is larger compared to previous monoclonal antibodies. Therefore a more effective desensitization against the allergen is expected.
In this phase II study the effects of 4 doses of QGE031 will be compared to those of a placebo. The change in sensitivity will be measured by a double-blind, placebo-controlled food challenge at baseline and after a 16 weeks treatment period.

Study objective

Primary: To characterize the QGE031 dose response relationship for the increase in the threshold dose of peanut protein that induces objective hypersensitivity reactions after treatment.
Secondary (only key parameters): The percentage of patients that experienced an increase from baseline to the end of treatment period in the threshold dose of at least 2 steps (or 10 fold) increase in peanut dose; safety and tolerability.

Study design

Multicenter randomized double-blind phase II parallel-group placebo-controlled study.
Randomisation (1:1:1:1:1) to:
• 14 mg QGE031 s.c. every 2 weeks
• 35 mg QGE031 s.c. every 2 weeks
• 98 mg QGE031 s.c. every 2 weeks
• 238 mg QGE031 s.c. every 2 weeks
• Placebo s.c. every 2 weeks.
Screening periode 2-3 weeks. Treatment period 18 weeks. Follow-up period 12 weeks.
Independent DSMB.
Interim-analyse planned, details not yet known (see protocol paragraph 9.8 (page 62).
Approx. 110 patients.

Intervention

Treatment with 1 of the 4 dosages of QGE031 or placebo.

Study burden and risks

Risk: Adverse effects of study medication en food challenge test and prick test.
Burden: Study duration 20-32 weeks. 13-18 visits. Duration 1-2 h, except 4 visits of 6-8 h.
Durng 18 weeks every 2 weeks sc injection of study medication (0,1-1,7

ml/injection).
Physical examination 7-9 times.
Blood tests 13 visits, 25-40 ml/occasion.
Optional pharmacogenetic/-genomics blood test (10 ml).
Pregnancy test (if relevant) 4 times.
Screening: stool sample.
ECG 2 times.
Pulmonary function test once.
Food challenge test 2 times (2 consecutive days/test).
Prick test 2 tomes.
Questionnaire 3 times.

Contacts

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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 and female subject 18-50y of age , who have a diagnosis of acute peanut allergy as manifested by urticaria, angioedema, respiratory tract symptoms, or hypotensive symptoms, with acute onset of symptoms after ingestion (up to 2h)
• Positive food challenge test at baseline
• Weight at least 40 kg.

Exclusion criteria

• Prior exposure to any monoclonal antibody treatment, e.g. prior QGE031 or Xolair use within 6 months prior to study entry
• Poorly controlled asthma
• Concomitant use of systemic immunosuppressant, beta blockers, ACE inhibitors or tricyclic antidepressants
• History of any of severe anaphylaxis as defined by hypoxia, hypotension, or neurological compromise (Cyanosis or SpO2 < 92% at any stage, hypotension, confusion, collapse, loss of consciousness; or incontinence)
• Women of child-bearing potential, unless using highly effective contraceptive measures.

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Will not start
Start date (anticipated):	13-04-2012
Enrollment:	24

Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	QGE031
Generic name:	QGE031

Ethics review

Approved WMO Date:	04-08-2011
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	10-11-2011
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	07-12-2011
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	17-04-2012
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	25-04-2012
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	clinicaltrials.gov; registratienummer n.n.b.
EudraCT	EUCTR2011-000631-92-NL
CCMO	NL37728.078.11