Omalizumab in Food Allergy - Retrospective data analysis (OFAR)

First published: 04/06/2025

Last updated: 04/06/2025

Study Finalised

Administrative details

EU PAS number

EUPAS1000000585

Study ID

1000000585

DARWIN EU® study

No

Study countries

- ☐ Germany
- ☐ Spain
- ☐ Switzerland

Study description

Retrospective, multi-center observational study conducted across four allergy departments in Europe (Berlin, Leipzig, Barcelona, and Basel).
The study included patients with IgE-mediated food allergy who were treated with omalizumab, either as monotherapy or in combination with oral immunotherapy (OIT) between 2002–2022. The study included adult patients diagnosed with IgE-mediated food allergy who received omalizumab treatment between 2002 and 2022.

Study status

Finalised

Research institutions and networks

Institutions

Institute of Clinical Pharmacology and Toxicology (PVZ FAKOS), Charite Universitaetsmedizin Berlin

Germany

First published: 16/04/2010

Last updated: 02/05/2012

Institution | Outdated | Educational Institution | ENCePP partner

Contact details

Study institution contact

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Study contact

Trialandresults.registries@novartis.com

Primary lead investigator

Novartis Clinical Disclosure Officer

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 04/10/2021

Study start date
Planned: 24/07/2022

Actual: 01/06/2023

Data analysis start date
Actual: 01/09/2023

Date of final study report
Actual: 22/04/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Novartis Pharma AG

Study protocol

Omalizumab Protocol final_Redacted.pdf (260.41 KB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Other study registration identification numbers and links

CIGE025A2010

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Study design:

Retrospective, multi-center observational study conducted across four allergy departments in Europe (Berlin, Leipzig, Barcelona, and Basel).
The study included patients with IgE-mediated food allergy who were treated with omalizumab, either as monotherapy or in combination with oral immunotherapy.

Main study objective:

To collect and analyse real-life data from patients who received omalizumab for the treatment of anaphylaxis.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Retrospective, multi-center observational study

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

OMALIZUMAB

Anatomical Therapeutic Chemical (ATC) code

(R03DX05) omalizumab

omalizumab

Medical condition to be studied

Food allergy

Additional medical condition(s)

IgE mediated food allergy

Population studied

Short description of the study population

The study included patients from 9 to 59 years diagnosed with IgE-mediated food allergy who received omalizumab treatment between 2002 and 2022. Participants were identified through institutional records from allergy departments in Berlin, Leipzig, Barcelona, and Basel.
Inclusion criteria required a confirmed history of food allergy—either with or without prior anaphylaxis—and treatment with omalizumab, either as monotherapy or in combination with oral immunotherapy.

Age groups

- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)
- Adults (18 to < 65 years)

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)

Estimated number of subjects

62

Study design details

Outcomes

Primary endpoints: The number of anaphylactic reactions during treatment (over a treating period of 3-6-12-24 months).

Secondary endpoints:

1. Quality of life outcomes during treatment (over a treating period of 3-6-12-24 months)
2. Collection of accidental reactions during treatment.
3. Allergen threshold levels before and during treatment.
4. Severity of anaphylactic reactions before and during treatment..

Data analysis plan

The data were collected and entered into an Excel database.

Analysis was conducted using IBM SPSS Statistics (version 27, Chicago, Ill)

Summary results

Sixty-two patients (female n= 39/62, 62.9%; mean age 30.6 years) were included into this analysis, most of whom were polysensitized to more than 2 food allergens (n=40/62, 64.5%); 45/62 patients (72.6%) received OMA in conjunction with OIT, while the remaining patients underwent OMA monotherapy.

The eliciting food allergens were tree nuts (n=27/62, 43.5%), cow’s milk (n=26/62, 41.9%), and vegetables (n=25/62, 40.3%). In most cases, OMA was

initiated with 300 mg q4w (n=51/62, 82.3%) dosing. Treatment was tolerated exceptionally well.
Fifty-two (52/62) patients (83.9%) were classified as treatment responders. Six (6/62) patients (9.7%) developed unresponsiveness, 6/62 (9.7%) had a reduction of the severity of food allergy, and 40/62 (64.5%) had no further anaphylactic reactions during treatment.
One (1/62) patient (1.6%) undergoing monotherapy was a non-responder, exhibiting repeated anaphylactic reactions to accidental exposures, and 10/62 patients (16.1%) reported anaphylactic reactions during treatment.
In most of these cases, cofactors (n=5/10, 50%) were present.

Documents

Study report

Abbreviated Report CIGE025A2010_signed MW_Redacted.pdf (492.79 KB)

Study publications

Alexiou et al. World Allergy Organization Journal (2025) 18:101048

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data sources (types)

Disease registry

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No