Real World Use, Effectiveness and Safety of Teprotumumab among Thyroid Eye Disease Patients treated in China BOAO Pilot Zone: A Retrospective Cohort Study (20240345)

First published: 30/06/2025

Last updated: 18/02/2026

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000625

Study ID

1000000625

DARWIN EU® study

No

Study countries

China

Study status

Ongoing

Research institutions and networks

Institutions

Amgen

United States

First published: 01/02/2024

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Institution

Contact details

Study institution contact

Global Development Leader Amgen Inc.

medinfo@amgen.com

Study contact

medinfo@amgen.com

Primary lead investigator

Global Development Leader Amgen Inc.

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 12/05/2025

Actual: 12/05/2025

Study start date
Planned: 30/07/2025

Actual: 02/07/2025

Data analysis start date
Planned: 30/09/2025

Actual: 15/09/2025

Date of final study report
Planned: 28/02/2026

Study protocol

20240345 Protocol-Published Original teprotumumab-trbw redacted.pdf (15.84 MB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

The main objective of this study is to assess proportion of patients with proptosis response as of
last intravenous infusion of teprotumumab.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name, other

Teprotumumab (TEPEZZA®)

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

TEPROTUMUMAB

Anatomical Therapeutic Chemical (ATC) code

(L04AG13) teprotumumab

teprotumumab

Medical condition to be studied

Graves' disease

Additional medical condition(s)

thyroid eye disease

Population studied

Age groups

- **Adult and elderly population (≥18 years)**
  - Adults (18 to < 65 years)
    - Adults (18 to < 46 years)
    - Adults (46 to < 65 years)
  - Elderly (≥ 65 years)
    - Adults (65 to < 75 years)
    - Adults (75 to < 85 years)
    - Adults (85 years and over)

Estimated number of subjects

10

Study design details

Outcomes

Secondary endpoints

- Baseline characteristics
- Teprotumumab use
- Proptosis
- Clinical Activity Score
- Diplopia
- Quality of life
- The incidence of adverse events between the administration of the first dose and 30 days after the last dose of teprotumumab
- Status of AE of interest up to 6 months after last infusion of teprotumumab

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Data analysis plan

All analyses will be descriptive in nature.

Data management

Data sources

Data source(s), other

Electronics health records of Boao Pilot Zone

Data sources (types)

Electronic healthcare records (EHR)

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Yes