BEL116559 Pooled Analysis of Belimumab Elderly Patients

First published: 27/08/2021

Last updated: 03/04/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS42275

Study ID

50560

DARWIN EU® study

No

Study countries

United Kingdom

Study description

Pooled analyses of elderly subjects (aged ≥ 65 years) who participated in selected belimumab clinical trials

Study status

Ongoing

Research institutions and networks

Institutions

GlaxoSmithKline (GSK)

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Institution

Contact details

Study institution contact

GSK Clinical Disclosure Advisor GSK Clinical Disclosure Advisor Pharma.CDR@gsk.com

Study contact

Pharma.CDR@gsk.com

Primary lead investigator

GSK Clinical Disclosure Advisor GSK Clinical Disclosure Advisor

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 01/07/2013

Actual: 01/07/2013

Study start date
Planned: 16/06/2013

Actual: 31/05/2013

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

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

GlaxoSmithKline

Study protocol

gsk-116559-reporting-and-analysis-plan-amend1-redact.pdf (323.86 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Main study objective:

To evaluate the safety of belimumab treatment on elderly subjects with SLE

Study Design

Non-interventional study design

Systematic review and meta-analysis

Study drug and medical condition

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

BELIMUMAB

Medical condition to be studied

Systemic lupus erythematosus

Additional medical condition(s)

ANCA vasculitis

Population studied

Age groups

- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Estimated number of subjects

219

Study design details

Outcomes

The incidence of treatment-emergent AEs, SLE Responder Index (SRI) response rate at Week 52

Data analysis plan

Series of aggregated analyses performed by pooling subject-level data from studies of interest, and conducting the analyses on the pooled data.

Documents

Study publications

D'Cruz D, Eriksson G, Green Y, Hammer A, Ji B, Meizlik P, Roth DA. Safety and e...

Wallace DJ, Atsumi T, Daniels M, Hammer A, Meizlik P, Quasny H, Schwarting A, Z...

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.

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