A Prospective and Retrospective, Observational Multicentre Ibalizumab Study of Efficacy (PROMISE)

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Study Ongoing

Administrative details

EU PAS number

EUPAS39579

Study ID

44292

DARWIN EU® study

No

Study countries

- [ ] Austria
- [ ] Belgium
- [ ] France
- [ ] Germany

- [ ] Italy
- [ ] Netherlands
- [ ] Norway
- [ ] Portugal
- [ ] Spain
- [ ] Switzerland
- [ ] United Kingdom

Study status

Ongoing

Research institutions and networks

Institutions

Chelsea and Westminster Hospital

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Institution

Networks

NEAT ID Foundation

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Graeme Moyle

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 14/07/2020

Study start date

Planned: 14/10/2021

Actual: 29/10/2021

Date of final study report

Planned: 31/12/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Theratechnologies Europe Limited

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Main study objective:

Primary Objective: To evaluate the long-term efficacy and durability of ibalizumab in combination with other antiretrovirals by comparing the virologic, immunologic and clinical outcomes of patients receiving ibalizumab treatment vs. matched patients not receiving ibalizumab.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

IBALIZUMAB

Medical condition to be studied

HIV infection

Population studied

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Estimated number of subjects

951

Study design details

Outcomes

Virologic, immunologic and clinical outcomes of patients receiving ibalizumab treatment vs. matched patients not receiving ibalizumab. Virologic, immunologic and clinical outcomes of patients before and after they receive ibalizumab treatment.

Data analysis plan

The Full Analysis set (FAS) will include all enrolled patients in cohort 2 and their match-control patients from cohort 1. The Per Protocol Analysis set (PP) will

include the subgroup of patients from cohort 2 who were prescribed ibalizumab as per the approved indication and their match-control patients from cohort 1. The All Enrolled set (AllE) will include all patients from cohort 1 (matched and unmatched patients) and cohort 2. The Safety Analysis set (SAF) will include all enrolled patients in cohort 2 who received at least one dose of ibalizumab.

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)

Other

Data sources (types), other

Prospective patient-based data collection

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