Evaluation of the immunomodulatory effects of therapy with Brentuximab (IMMBRE)

First published: 25/05/2016

Last updated: 25/05/2016

Study Finalised

Administrative details

EU PAS number

EUPAS13579

Study ID

13580

DARWIN EU® study

No

Study countries

☐ Italy

Study description

Evaluation of CD30 as a marker of immunosuppressive cells by analysis of the potential immunomodulatory effect of treatment with Brentuximab in patients with lymphoma

Study status

Finalised

Research institutions and networks

Institutions

Fondazione IRCCS Istituto Nazionale dei Tumori

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Licia Rivoltini

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 18/05/2016

Actual: 25/05/2016

Study start date
Planned: 19/05/2016

Actual: 25/05/2016

Date of final study report
Planned: 31/05/2019

Actual: 25/05/2016

Sources of funding

- Pharmaceutical company and other private sector
- Non-for-profit organisation (e.g. charity)
- EU institutional research programme
- Other

More details on funding

Name of pharmaceutical company(ies), Charities, Government body, Research councils, EU funding scheme not provided; Other: funding of the facility

Regulatory

Was the study required by a regulatory body?

No

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Other

If ‘other’, further details on the scope of the study

Evaluation of CD30 as a marker of immunosuppressive cells

Data collection methods:

Primary data collection

Main study objective:

Evaluation of CD30 as a marker of immunosuppressive cells by analysis of the potential immunomodulatory effect of treatment with Brentuximab in patients with lymphoma

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

ADCETRIS

Medical condition to be studied

T-cell lymphoma

Hodgkin's disease stage I

Hodgkin's disease stage II

Hodgkin's disease stage III

Hodgkin's disease stage IV

Population studied

Short description of the study population

Adult patients with lymphoma treated with Brentuximab.

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)

Special population of interest

Other

Special population of interest, other

Lymphoma patients

Estimated number of subjects

30

Study design details

Data analysis plan

Evaluation of CD30 as a marker of immunosuppressive cells by analysis of the potential immunomodulatory effect of treatment with Brentuximab in patients with lymphoma

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