International documentation on the use of Cytotect CP® Biotest for patients after lung and heart transplantation (NIS-021 Cytotect)

First published: 16/02/2023

Last updated: 23/04/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS47920

Study ID

1000000049

DARWIN EU® study

No

Study countries

- [ ] Austria
- [ ] Belgium
- [ ] Croatia

- [ ] Germany
- [ ] Italy
- [ ] Spain
- [ ] United Kingdom

Study description

Non-interventional, prospective/retrospective, single-arm, uncontrolled, multi-centre, international, post approval study. Assessment of the real-world usage of Cytotect CP® Biotest in patients after heart and lung transplantation. The aim of this NIS is to understand the actual usage of Cytotect in the context with other CMV treatments and immunosuppressive regimens and to draw conclusions on the real-world relevance, efficacy and safety of the different prophylaxis and treatment approaches.

Study status

Ongoing

Research institutions and networks

Institutions

Biotest

First published: 01/02/2024

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Institution

26 centres are involved in this study

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Markus Johannes Barten

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 30/11/2021

Actual: 30/11/2021

Study start date

Planned: 01/05/2022

Actual: 01/01/2023

Data analysis start date

Planned: 31/10/2026

Date of final study report

Planned: 15/03/2027

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Biotest GmbH

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 type:

Non-interventional study

Scope of the study:

Disease epidemiology

Effectiveness study (incl. comparative)

Main study objective:

Prospective documentation of the real-world usage of Cytotect for prophylaxis, pre-emptive treatment and treatment of CMV infection after heart transplantation (HT) and lung transplantation (LT).

Population studied

Short description of the study population

Male, female and diverse patients receiving CMV prophylaxis or treatment with Cytotect after Lung and Heart Transplantation at specialised transplant centres.

Age groups

Adolescents (12 to < 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

500

Study design details

Outcomes

Primary outcome: Proportion of patients requiring treatment for CMV until month 12 after Cytotect prophylaxis start.

Secondary outcome: Proportion of patients developing CMV DNAemia until month 12 and 24 after Cytotect prophylaxis start.

Data analysis plan

All analyses will be performed in an exploratory sense. Since there are no confirmatory analyses planned, hypotheses are not formulated. Data will be analysed using descriptive statistics. For continuous variables, mean, standard deviation, minimum, maximum, median, 25% and 75% percentiles will be presented. Qualitative and categorical variables will be presented by means of absolute and relative frequencies. A statistical analysis plan will be prepared.

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