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

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## Administrative details

EU PAS number	
EUPAS47920	
Study ID	
100000049	
DARWIN EU® study	
No	
Study countries	
Austria	
Belgium	
Croatia	

Germany
Italy
Spain
United Kingdom

#### **Study description**

Non-interventional, prospective/retrospective, single-arm, uncontrolled, multicentre, 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

**Last updated:** 01/02/2024

Institution

26 centres are involved in this study

## Contact details

### **Study institution contact**

Artur Bauhofer nis@biotest.com

Study contact

nis@biotest.com

### **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