Comparative Effectiveness and Safety of Immunosuppressive Drugs in Transplant patients (CESIT)

First published: 11/12/2020

Last updated: 13/03/2025

Study Ongoing

Administrative details

EU PAS number

EUPAS38308

Study ID

41064

DARWIN EU® study

No

Study countries

☐ Italy

Study description

CESIT is an Italian multicenter retrospective cohort study on the use of immunosuppressive drugs in transplant patients, based on information available in regional administrative healthcare databases and on National Transplant Information System (SIT). The aims are: 1) to describe the prescriptive patterns of immunosuppressive drug regimens in different transplant settings (kidney, lung, liver, heart) used in maintenance phase and to identify patient characteristics associated to these patterns in the four Italian regions (Lombardy, Veneto, Lazio, Sardinia), accounting for over 20 million residents, 2) to compare the risk-benefit profile of different immunosuppressive therapeutic regimens, with a focus on generics/branded and special populations (paediatric and elderly) 3) to evaluate data validity and generalizability through SIT All transplant patients residing in the regions involved in the study will be identified through an algorithm considering all the hospitalizations, occurred over the years 2009–2019, reporting a transplantation procedure . Comorbidity will be defined from Hospital discharge records (ICD-9-CM codes), disease specific copayment exemptions, and, as far as possible, disease specific drug treatments and NTIS. Drug utilisation patterns will be based on drugs (ATC codes) prescribed to outpatients using the DDDs. Specific outcomes, such as organ survival and rejection, will be identify by SIT. Safety and effectiveness will be investigated using a new-user approach and applying both, intention-to-treat and as-treated analysis. Data and analysis will be managed through a common data model, with shared data scripts, performing the analysis and pooling aggregated anonymous data to obtain overall results.

Study status

Ongoing

Research institutions and networks

Institutions

Department of Epidemiology of the Regional Health Service - Lazio

Italy

First published: 23/03/2010

Last updated: 22/06/2018

Institution | **EU Institution/Body/Agency** | **ENCePP partner**

Pharmacoepidemiology Unit - National Centre for Epidemiology, Surveillance and Health Promotion, Istituto Superiore di Sanità (ISS)

Italy

First published: 23/03/2010

Last updated: 18/09/2023

Institution | **Educational Institution** | **Laboratory/Research/Testing facility** | **ENCePP partner**

Department of Epidemiology of the Regional Health Service - Lazio

Italy

First published: 23/03/2010

Last updated: 22/06/2018

Institution | EU Institution/Body/Agency | ENCePP partner

Pharmacology Unit - Veneto Pharmacovigilance Centre (Pharmacol UNIVR), University Hospital Verona

Italy

First published: 25/10/2022

Last updated: 13/03/2025

Institution | Educational Institution | Hospital/Clinic/Other health care facility | ENCePP partner

National transplant center (CNT), National Institute of Health Rome, Italy, Pharmacoepidemiology Unit, National Centre for Drug Research and Evaluation, National Institute of Health Rome, Italy, Epidemiology Observatory - Department of Health of Lombardy Region Milan, Italy, Department of Diagnostics and Public Health,

Section of Pharmacology, University of Verona Verona, Italy, Epidemiological Department, Azienda Zero, Veneto Region Padua,Italy, Regional Councillorship of Health 'Regione Autonoma della Sardegna' Cagliari, Italy

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Valeria Belleudi

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 23/09/2020

Actual: 23/09/2020

Study start date

Planned: 12/04/2021

Actual: 04/05/2021

Data analysis start date
Planned: 10/06/2021

Date of interim report, if expected
Planned: 23/09/2021

Date of final study report
Planned: 30/09/2022

Sources of funding

- Other

More details on funding

Italian Medicines Agency, Regional Drug Departments

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:

Drug utilisation

Effectiveness study (incl. comparative)

Main study objective:

1. To describe the prescriptive patterns of immunosuppressive drug regimens in different transplant settings (kidney, lung, liver, heart) used in maintenance phase and identify patient characteristics associated to these patterns in the four Italian regions 2. To compare the risk-benefit profile of different immunosuppressive therapeutic regimens in transplant patients

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Transplant

Population studied

Age groups

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

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

Hepatic impaired

Renal impaired

Estimated number of subjects

7000

Study design details

Outcomes

Transplant rejection, organ survival, use of steroids or immunoglobulin or antibodies for acute rejection, overall mortality, infections, diabetes incidence, cancer incidence (including skin cancer and lymphoma), hypertension incidence,incident statin use, Use of health care services, adverse drug reactions, lymphoproliferative disease, hyperglycemia, magnesium metabolism disorders, recurrence of HCV

Data analysis plan

Data will be organised and managed through a common data model. Analysis will be performed running the shared scripts at local level and pooling

aggregated data at the end. Drug utilization will be defined on the basis of DDDs. CER will be performed through both a multivariate models and a propensity matched cohort design (head-to-head comparison between different drug groups/drugs). Patients in the compared exposure groups will be propensity matched. Intention-to-treat and As-treated analyses will be performed using Cox proportional Hazard models (HRs and 95%CIs).

Data management

Data sources

Data source(s)

Mortality Information System

Drug claims information system

Hospital Information System

Healthcare Emergency Information System

Data source(s), other

MIS, PHARM, HIS, HEIS

Data sources (types)

Administrative healthcare records (e.g., claims)

Disease registry

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