ACCELERATE: AN INTERNATIONAL, OBSERVATIONAL REGISTRY FOR PATIENTS WITH CASTLEMAN DISEASE

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Study Finalised

Administrative details

EU PAS number

EUPAS14776

Study ID

48792

DARWIN EU® study

No

Study countries

France

Germany

Italy

Norway

Spain

United Kingdom

Study description

The ACCELERATE patient registry will give Castleman Disease (CD) patients and families the opportunity to contribute their medical data to improve understanding of CD. The patient registry will obtain data from 500 patients worldwide with CD over a 5-year period. Main objectives: 1. Improve our understanding of the natural history, pathogenesis, and treatment of CD 2. Carefully define clinical features and biomarkers associated with CD to inform diagnostic criteria and identify subgroups of patients 3. Collect data on survival of Castleman disease patients and quality of life metrics 4. Build capacity for collaboration by collecting clinical data and tracking the location of all available tissue samples for future studies Patients of any age with CD and family members of deceased CD patients are invited to join the registry. The inclusion criteria requires that every patient have a pathology report mentioning or suggesting “Castleman disease” that is not limited to cutaneous involvement and that the patient or family member provide informed consent. Patients located in the following countries (Germany, France, Italy, UK, Spain) are recommended to contact the specific investigators at our 10 sites. Participating physicians will consent patients, enter medical record data into the registry, and update medical records periodically. Patients located anywhere outside of the 5 countries specified above will be able to directly enroll themselves at http://www.cdcn.org/accelerate and asked to provide their medical records to University of Pennsylvania for data extraction. All patients in both groups will be asked to complete questionnaires every three months about their symptoms, treatments, and experiences with CD. Complete participant information will be stored in a secure database. Every 6 months an interim analysis will be performed.

Study status

Finalised

Research institutions and networks

Institutions

Hopital Cl Huriez Lille, France, Hopital Saint-Louis Paris, France, Infektionsmedizinisches Centrum Hamburg, Germany, Universitätsklinikum Münster Münster, Germany, King's College Hospital London, UK, Oslo universitetssykehus Oslo, Norway, Hospital Universitario Ramón y Cajal Madrid, Spain, University of Turin Torino, Italy, University of Bologna Bologna, Italy

Networks

Castleman Disease Collaborative Network

Contact details

Study institution contact
David Fajgenbaum davidfa@pennmedicine.upenn.edu

Study contact

davidfa@pennmedicine.upenn.edu

Primary lead investigator

David Fajgenbaum

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 10/02/2016

Study start date
Actual: 29/12/2016

Data analysis start date
Planned: 23/11/2018

Date of interim report, if expected
Planned: 01/06/2019

Date of final study report
Planned: 01/05/2023

Actual: 01/05/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

EUSA Pharma

Study protocol

ACCELERATE_Registry_Approved_Protocol_amended042516 (2).pdf (3.49 MB)

ACCELERATE_current approved 20180611.pdf (7.16 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 1 (imposed as condition of marketing authorisation)

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Data collection methods:

Primary data collection

Main study objective:

Primary: •To collect real-world demographic, clinical, laboratory, Patient Reported Outcome (PRO), and treatment data on patients with Castleman disease. Secondary: Define clinical features/biomarkers associated with Castleman disease • Assess their effectiveness and safety profiles of Castleman disease treatment • Collect data on survival and quality of life metrics

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Observational, multi-national, multicenter, prospective, natural history study

Study drug and medical condition

Medical condition to be studied

Castleman's disease

Population studied

Short description of the study population

The study population included patients of any age with Castleman disease from Germany, France, Italy, UK, Spain.

Inclusion Criteria:

· Person of any age

· Have a reference pathology report suggesting “Castleman disease” not limited to cutaneous involvement only that can be uploaded

· Be able to provide electronic informed consent, as per local regulations

Deceased patients may also be enrolled when a reference pathology report suggesting “Castleman disease” can be supplied or when the ART is able to locate and upload such a pathology report.

Exclusion Criteria:

Because this registry is designed to provide as wide a picture of routine clinical practice as possible, inclusion criteria are set deliberately wide and there are no exclusion criteria.

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

Renal impaired

Hepatic impaired

Immunocompromised

Pregnant women

Other

Special population of interest, other

Patients with Castleman disease

Estimated number of subjects

1000

Study design details

Data analysis plan

The statistical analysis plan for this registry aims to include analyses of demographics and baseline disease characteristics, treatment effectiveness data, patient reported outcome data, biologic parameters, safety data, and comparability between treatment groups.

Documents

Study, other information

Fajgenbaum Haematology.pdf (996.71 KB)

LiuFajgenbaum_Lancet Haematology.pdf (235.16 KB)

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.

Composition of steering group and observers

ACCELERATE study ASC Members.pdf (236.33 KB)

Data sources

Data sources (types)

Other

Data sources (types), other

Medical records, Prospective clinical notes, Physician surveys

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