Disease Registry for Patients with Digital Ulcers associated with Systemic Sclerosis (DUO Registry)

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Study **Finalised**

Administrative details

EU PAS number

EUPAS4619

Study ID

28356

DARWIN EU® study

No

Study countries

☐ Austria

☐ Czechia

☐ Denmark

☐ Finland

- ☐ France
- ☐ Germany
- ☐ Greece
- ☐ Ireland
- ☐ Italy
- ☐ Netherlands
- ☐ Norway
- ☐ Portugal
- ☐ Slovakia
- ☐ Slovenia
- ☐ Spain
- ☐ Sweden
- ☐ Switzerland
- ☐ United Kingdom

Study description

The registry is a multi-center, prospective, observational, non-interventional program and was designed to document adherence to the Summary of Product Characteristics (SmPC) requirements for liver function tests, pregnancy testing and the use of adequate contraception in DU/ SSC patients exposed to Tracleer, to collect Safety relevant information from patients treated with Tracleer and to obtain data on DU disease history, baseline characteristics (collected at the time of enrolment into the registry), and disease course irrespective of treatment regimen, in patients with DU/ SSC.Inclusion criteria: At time of enrolment the patient must present with Systemic sclerosis and ongoing digital ulcer disease.Exclusion criteria: Patients refused to sign the patient informed consent.

Study status

Finalised

Research institutions and networks

Institutions

Actelion Pharmaceuticals

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Institution

Multiple centres: 428 centres are involved in the study

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Eric Schoenamsgruber

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 10/03/2008

Study start date

Actual: 14/04/2008

Date of final study report

Actual: 02/03/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Actelion

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Drug utilisation

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Data collection methods:

Combined primary data collection and secondary use of data

Main study objective:

For Tracleer treated patients only: to document adherence to the Summary of Product Characteristics (SmPC) requirements (liver enzymes monitoring, pregnancy testing and contraception methods) and to describe the occurrence of specific safety (e.g. pregnancy and discontinuation reasons).For ALL patients: to describe DU disease history, baseline status and disease course.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Scleroderma associated digital ulcer

Population studied

Short description of the study population

Patient with Systemic sclerosis and ongoing digital ulcer disease at time of enrolment.

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)

Estimated number of subjects

6108

Study design details

Outcomes

Proportion compliance to SmPC, occurrence of new DUs, and complications and interventions associated with DUs.

Data analysis plan

Safety of Tracleer: cumulative event rates, Adherence to Tracleer SmPC requirements: Proportion of patients with contraception, pregnancy testing and LFT monitoring, DU disease history, patient entry characteristics and disease course: descriptive statistics by treatment group, time to event estimate.

Data management

Data sources

Data sources (types)

Disease registry

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

Unknown