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ZEUS - ZINBRYTA real world use study in Germany

Submission date	Recruitment status	[ ] Prospectively registered
26/04/2017	Stopped	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
22/05/2017	Stopped	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
30/10/2019	Nervous System Diseases	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Multiple sclerosis (MS) is a chronic (long-term) inflammatory disease of the central nervous system (brain and/or spinal cord). More than 2 million people are affected worldwide. Most MS patients (90%) suffer from relapsing remitting MS, where they have episodes of new or worsening symptoms (e.g., vision problems, numbness, muscle weakness), known as relapses, which then slowly improve. Relapses are often reversible to begin with, but over time there is a slow deterioration of neurological functions. The aim of this study is to collect further data on the effectiveness and safety of the drug daclizumab, which is used to treat relapsing MS.

Who can participate?
Patients aged 18 and over with relapsing remitting MS who are starting treatment with daclizumab

What does the study involve?
Participants are followed for up to 60 months after starting treatment or until death, withdrawal, or the participants is considered lost to follow up, whichever occurs first. Follow up is planned regardless of whether treatment with daclizumab is stopped, unless informed consent is withdrawn or a participant joins another study. Assessments are completed and data is collected at the start of the study, 3 and 6 months after starting daclizumab treatment, and every 6 months thereafter for up to 60 months. The proportion of patients who still are on treatment with daclizumab, their reasons for stopping treatment, treatment adherence, relapses, progression of disability and side effects are all measured at each visit.

What are the possible benefits and risks of participating?
No benefits or risks are expected.

Where is the study run from?
160 sites, led by Carl Gustav Carus Management GmbH, university hospital, clinic for neurosciences (Germany)

When is the study starting and how long is it expected to run for?
December 2016 to June 2023

Who is funding the study?
Biogen GmbH (Germany)

Who is the main contact?
Dr Karin Rehberg-Weber
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
EUR-ZIN-16-11024

Study information

Scientific Title
A Phase 4, 5-year, multicenter, prospective, observational, single-cohort study to document utilization, effectiveness and safety of daclizumab in subjects with relapsing forms of MS in clinical practice in Germany

Acronym
ZEUS

Study objectives
To evaluate persistence on treatment with daclizumab in RMS patients starting therapy in clinical practice.
Primary endpoint: proportion of patients who are on treatment with daclizumab at Month 24 after treatment initiation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics committee at the Technical University Dresden (Technische Universität Dresden), 15/12/2016, ref: EK 474112016

Primary study design
Observational

Study design
Multicenter prospective observational single-cohort study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Relapsing remitting multiple sclerosis (RMS)

Interventions
Non-interventional, observational study; diagnosis and treatment are done only in compliance with clinical routine

This is a multicenter, prospective, observational, single-cohort study to document utilization, effectiveness and safety of daclizumab monotherapy in patients with RMS who have been newly prescribed treatment with daclizumab in a routine clinical practice setting and according to locally approved prescribing information.

Approximately 1,000 subjects will be enrolled over an 18-month period from about 160 sites in Germany and will be followed for up to 60 months since initiation of treatment or until death, withdrawal, or the subject is considered lost to follow up, whichever occurs first. Follow up is planned regardless whether treatment with daclizumab is discontinued, unless informed consent is withdrawn or a subject is enrolled in another investigational trial.

The Prescribing Physicians will participate in the study as Investigators.

Subjects will be enrolled after the decision to treat with daclizumab has been made, or as soon as possible after the start of daclizumab treatment as long as complete demographic and baseline information as requested per study protocol is available; however, before their fourth dose of daclizumab at the latest.

Assessments will be completed and data collected at baseline, 3 and 6 months after initiation of daclizumab treatment and approximately every 6 months thereafter for up to completion of 60 months.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Daclizumab

Primary outcome(s)
Proportion of patients who are on treatment with daclizumab at Month 24 after treatment initiation (current therapy is documented at each visit: baseline, 3 months, 6 months, and every 6 months until month 60)

Key secondary outcome(s)
1. Proportion of patients who are on treatment with daclizumab at Month 60 after treatment initiation (current therapy is documented at each visit)
2. Reasons for stopping a therapy with daclizumab (if applicable); therapy is documented at each visit
3. Therapy adherence, self reported by patients in a diary and documented by participating physician at each visit
4. Relapse rates per year and percentage of patients without relapse; time until first relapse; relapses are documented at each visit
5. Progression of disability (24 weeks after start of therapy), measured by EDSS score
6. AEs and SAEs, documented at each visit
7. Complete blood count, lymphocyte sub-populations, measured at each visit
8. Patient reported outcomes:
8.1. Patients' views regarding consequences of MS, measured using Multiple Sclerosis Impact Scale (MSIS-29)
8.2. Quality of life, measured using EuroQoL-5D (EQ-5D)
8.3. Treatment satisfaction, measured using Treatment Satisfaction Questionnaire for Medication (TSQM 1.4)
8.4. Cognitive functions, measured using the Symbol Digit Modalities Test (SDMT)
Visits take place at baseline, 3 months, 6 months, and every 6 months until month 60

Completion date
31/10/2019

Reason abandoned (if study stopped)
Objectives no longer viable

Eligibility

Key inclusion criteria
1. Ability to understand the purpose of the study and provide signed and dated informed consent and authorization to use confidential health information in accordance with national and local subject privacy regulations
2. Start of daclizumab therapy in accordance with local prescribing information; the decision for the daclizumab therapy must be made before study inclusion; patients can be enrolled until before administration of fourth daclizumab dose - provided baseline data are available
3. Aged at least 18 years at time of enrolment; no upper age limit

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group

Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Missing ability or willingness to give informed consent after information about the study
2. Missing eligibility for participation from physician's point of view
3. Contraindication to treatment with daclizumab or diseases which are contraindicated according to the local prescribing information
4. Concomitant therapy with another disease-modifying MS-therapy
5. Current or planned participation in a clinical interventional study

Date of first enrolment
15/12/2016

Date of final enrolment
02/03/2018

Locations

Countries of recruitment
Germany

Study participating centre
Carl Gustav Carus Management GmbH, university hospital, clinic for neurosciences
Fetscherstraße 74
Dresden
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Sponsor information

Organisation
Biogen GmbH

ROR
https://ror.org/014rfma52

Funder(s)

Funder type
Industry

Funder Name
Biogen GmbH

Results and Publications

Individual participant data (IPD) sharing plan
The data will be held by the sponsor (Biogen Germany) and published in articles, abstracts and publications. Data for individuals will not be available due to data protection reasons.

IPD sharing plan summary
Not expected to be made available