Trial Description

Title

Documentation of specific indications of lipoprotein apheresis - Real World Study

Trial Acronym

RWS

URL of the trial

http://not applicable

Brief Summary in Lay Language

In this study, data are to be collected from patients who are treated with lipoprotein apheresis due to different diseases (e.g. due to a lipid metabolism disorder). Such diseases may include e.g. inherited lipid metabolism disorders such as familial hypercholesterolaemia (highly increased LDL cholesterol), hypertriglyceridaemia (highly increased triglycerides), or Refsum's disease. For this purpose, documents have been prepared to enable this data collection. The aim of this documentation is to document the use of lipoprotein apheresis in patients with various diseases. For this purpose, findings, results and laboratory values from examinations or treatments, which are performed in patients anyway, are recorded. When participating in the study, no additional examinations or treatments are performed on the patient. The evaluation of the data is intended to provide further insights into the efficacy and tolerability of the therapy when used in practice. Target parameters to be documented in this study are:
• Effectiveness of lipoprotein apheresis by clinical parameters (e.g., occurrence of cardiovascular events, course of disease-specific symptoms, necessary interventions)
• Safety and tolerability based on therapies
• Disease-specific laboratory parameters before, after and during therapy (e.g., LDL cholesterol, lipoprotein(a), triglycerides), concomitant medication.

Brief Summary in Scientific Language

Within the scope of this documentation, patients with pathophysiological conditions (for example due to a lipid / lipid metabolism disease) are to be treated with lipoprotein apheresis. Underlying diseases may include e.g. familial hypercholesterolaemia, hypertriglyceridaemia or Refsum's disease. For this purpose, documents have been prepared which make this retrospective-prospective documentation possible. The aim of this non-interventional documentation is to document the use of lipoprotein apheresis in patients with different indications. The evaluation of the data is intended to provide further insights into the efficacy and tolerability of the therapy in the clinical routine. Target parameters to be documented in this study are:
• efficacy of lipoprotein apheresis by clinical parameters (e.g., occurrence of cardiovascular events, course of disease-specific symptoms, necessary interventions)
• Safety and tolerability based on reference apheresis

• Disease-specific laboratory parameters before, after and during therapy (e.g., LDL cholesterol, lipoprotein(a), triglycerides), concomitant medication.

Organizational Data

- DRKS-ID: **DRKS00011704**
- Date of Registration in DRKS: **2017/02/09**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **no**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **017/1007 , Freiburger Ethik-Kommission International**

Secondary IDs

- Universal Trial Number (UTN): **U1111-1192-3574**

Health condition or Problem studied

- ICD10: **E78.0 - Pure hypercholesterolaemia**
- ICD10: **G60.1 - Refsum disease**
- ICD10: **E78.1 - Pure hyperglyceridaemia**
- ICD10: **E78.2 - Mixed hyperlipidaemia**
- ICD10: **E78.3 - Hyperchylomicronaemia**
- ICD10: **E78.4 - Other hyperlipidaemia**
- ICD10: **E78.5 - Hyperlipidaemia, unspecified**
- ICD10: **E78.8 - Other disorders of lipoprotein metabolism**
- ICD10: **E78.9 - Disorder of lipoprotein metabolism, unspecified**

Interventions/Observational Groups

- Arm 1: **The data of patients with the indication of lipoprotein apheresis are documented:**

  Retrospective part:
  • Before the onset of lipoprotein apheresis treatment; (e.g., lipid parameters, mutations, first cardiovascular manifestations, or other disease-specific manifestations and symptoms, events and interventions, relevant adjunctive diseases, medication).

  Prospective part:
  • Clinical history of lipoprotein apheresis (e.g., cardiovascular events or

interventions, relevant companion diseases, specific pediatric aspects, medication).

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **Single arm study**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Uncontrolled/Single arm**
- Purpose: **Prevention**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **No**

Primary Outcome

Documentation of the efficacy of lipoprotein apheresis in different indications; Clinical and laboratory parameters.

Secondary Outcome

• Effectiveness of lipoprotein apheresis by clinical parameters (e.g., occurrence of cardiovascular events, course of disease-specific symptoms)
• Documentation of safety and tolerability using reference apheresis treatments
• documentation of disease-specific laboratory parameters before, during and after therapy (e.g., LDL cholesterol, lipoprotein(a), triglycerides)

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Doctor's Practice **Essen**
- Doctor's Practice **Passau**
- Doctor's Practice **Kempten**
- Doctor's Practice **Saarlouis**
- Doctor's Practice **Tangermünde**

- Medical Center **Dresden**

Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2017/02/15**
- Target Sample Size: **100**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **90 Years**

Additional Inclusion Criteria

In the case of the patients examined in the context of this documentation, the indication for lipoprotein apheresis exists. The patients covered in this documentation are routinely treated within the contractual medical care of lipoprotein apheresis. General inclusion / exclusion criteria:
• The respondent is in a position to give his / her informed consent to study participation after elucidation.
• Male and female subjects, age ≥ 18 years.

Exclusion criteria

The following criteria lead to the exclusion / withdrawal of the study for the person concerned:
• The subject withdraws his consent.
• Any medical or non-medical reason which, in the opinion of the examiner, requires the completion of the documentation for the subject.
• The investigation can be terminated at the beginning at any time by the sponsor or the director of the documentation.

Addresses

- **Primary Sponsor**

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Sources of Monetary or Material Support

■ **Commercial (pharmaceutical industry, medical engineering industry, etc.)**

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Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

- Approval of ethics comm. (mandatory for transfer to Studybox) **Ethikvotum**

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*