A Non-interventional Implementation Study to Evaluate Treatment With Inclisiran (Leqvio®) and Other Lipid Lowering Treatments in a Real-world Setting

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A Non-interventional Implementation Study to Evaluate Treatment With Inclisiran (Leqvio®) and Other Lipid Lowering Treatments in a Real-world Setting (VICTORION-Implement)
ClinicalTrials.gov Identifier:
NCT05362903
Novartis Reference Number:CKJX839A1DE01
See if you Pre-qualify
All compounds are either investigational or being studied for (a) new use(s). Efficacy and safety have not been established. There is no guarantee that they will become commercially available for the use(s) under investigation.

Study Description

This is a multicenter, non-randomized, non-interventional three-cohort study with prospective collection of primary data of treatment with newly initiated oral Lipid lowering treatment on top of a statin (Oral LLT cohort), newly initiated Inclisiran (Inclisiran cohort) and newly initiated Inclisiran on top of lipid apheresis (Apheresis plus Inclisiran cohort) in routine clinical care. All procedures, treatment adaptions and laboratory assessments are part of clinicla routine and conducted independent of this study.

Condition
Hypercholesterolemia
Overall Status
Recruiting
Number of Participants
2030
Start Date
Jan 28, 2022
Completion Date
Dec 01, 2025
Gender
All
Age(s)
18 Years - 100 Years (Adult, Older Adult)

Interventions

Other

Inclisiran

Prospective observational cohort study. There is no treatment allocation. Patients administered Inclisiran by prescription will be enrolled.

Eligibility Criteria

Inclusion Criteria:

1. Patients who provide written informed consent to participate in the study
2. Male or female patients ≥ 18 years of age
3. Oral LLT Cohort: Patients with documented ASCVD newly initiated on an oral lipid lowering treatment on top of a statin (e.g. ezetimibe, bempedoic acid, cholestyraimin)
4. Inclisiran Cohort: Patients newly initiated on Inclisiran fulfilling the restricted reimbursement criteria or individual access requirements who are not at LDL-C goal as per their CV risk as recommended in the 2019 EAS/ESC guidelines (Mach et al., 2020). At least 60% of the documented patients must be PCSK9-inhibitor naive
5. Apheresis plus Inclisiran Cohort: Patients with Inclisiran on top of regular weekly or bi-weekly lipoprotein apheresis (LDL-c or LP(a)).

Exclusion Criteria:

1. Oral LLT Cohort: Patients who receive a PCSK9-mAB or other PCSK9-targeted therapy
2. Inclisiran 1 Cohort: current or previous PCSK9-targeted treatment
3. Contraindication for Inclisiran according to the SmPC
4. Patients who have received Inclisiran previously
5. Patients with homozygous FH
6. Any underlying known disease, or surgical, physical, or medical condition that, in the opinion of the investigator (or delegate) might interfere with interpretation of the clinical study results.
7. Simultaneous or planned participation in an interventional research study

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