The Belgian REAL (BE.REAL) Registry

Last Update: Jan 14, 2025
A Belgian Registry to Evaluate the Real Life Treatment With Inclisiran on Top of Standard of Care Lipid-lowering Therapy in Patients With Atherosclerotic Cardiovascular Disease
ClinicalTrials.gov Identifier:
NCT05726838
Novartis Reference Number:CKJX839D1BE01
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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 an observational non-interventional study. The visit schedule is according to the routine clinical practice. Only data corresponding to study variables within the specified study period will be collected.

The study will recruit patients into one single cohort: Inclisiran in combination with other LLTs. The patients will receive Inclisiran therapy as per the approved label and Belgian reimbursement conditions. The study aims to assess the effectiveness, safety and adherence for Inclisiran in combination with lipid-lowering therapy (LLT) under conditions of routine clinical practice. The Inclisiran cohort will include patients receiving Inclisiran therapy as per the approved label independently of background Standard of Care (SoC) therapy. This study will include both primary data collection and secondary use of data.

* Prospective data collection: Patients will be enrolled over a period of 6 months between 01-December-2022 and 31-May-2023 and will have a maximum follow-up of 39 months or 8 injection visits.
* Retrospective data collection: Retrospective data will also be captured for patients with a first prescription between 01-May-2022 and study start and will be followed up for a maximum of 39 months to assess for study outcomes. In this case, baseline data and data of the first injection visits will be retrieved by the physician and captured in the Clinical Report Form (CRF), followed by prospective data collection during the rest of the follow-up period.

Condition
Atherosclerotic Cardiovascular Disease
Overall Status
Recruiting
Number of Participants
300
Start Date
Apr 15, 2022
Completion Date
Jul 01, 2026
Gender
All

Age(s)
18 Years - 99 Years (Adult, Older Adult)

Interventions

Other

Inclisiran

There is no treatment allocation. Patients administered inclisiran by prescription will be enrolled. The patients will receive inclisiran therapy as per the approved label and Belgian reimbursement conditions.

Eligibility Criteria

Inclusion Criteria:

1. Patients who are 18 years or older.
2. Patients with Atherosclerotic Cardiovascular Disease (ASCVD) who are eligible for commercially available Leqvio, as defined by the reimbursement criteria:

Patients with ASCVD documented by previous coronary heart disease (CHD), cerebrovascular disease or peripheral artery disease (PAD) and LDL-C ≥ 100mg/dL despite a treatment of min 6 weeks with max tolerated statin (unless intolerance or contra-indication) in combination with ezetimibe (unless intolerance or contra-indication).
3. Heterozygous Familial Hypercholesterolemia (HeFH) patients with documented ASCVD who are eligible for commercially available Leqvio.
4. Patients who provide written informed consent to participate in the study.

Exclusion Criteria:

1. Patients who have received Inclisiran previously.
2. Patients participating in a clinical trial with investigational product.
3. Heterozygous Familial Hypercholesterolemia patients without established Atherosclerotic Cardiovascular Disease.

Belgium

Novartis Investigative Site

Recruiting

Kortrijk,8500,Belgium

Novartis Investigative Site

Recruiting

Bruxelles,1020,Belgium

Novartis Investigative Site

Recruiting

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Edegem,2650,Belgium

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Recruiting

Liege,4000,Belgium

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Genk,3600,Belgium

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Turnhout,2300,Belgium

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Gent,9000,Belgium

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Aalst,9300,Belgium

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Recruiting

Yvoir,5530,Belgium

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Haine-saint-Paul,7100,Belgium

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Anderlecht,1070,Belgium

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Huy,4500,Belgium

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Recruiting

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Worldwide Contacts

If the location of your choosing does not feature any contact detail, please reach out using the information below.

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Source URL: *https://prod1.novartis.com/clinicaltrials/study/nct05726838*

List of links present in page

1. https://clinicaltrials.gov/ct2/show/NCT05726838
2. #trial-eligibility
3. tel:+41613241111
4. mailto:novartis.email@novartis.com