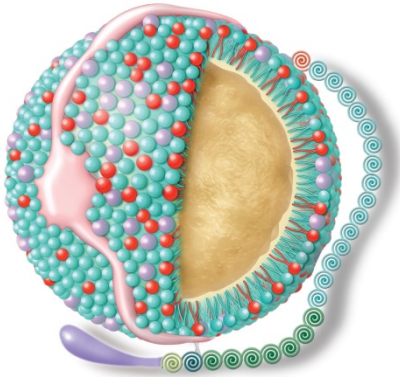
Adjusted Inclusion Criteria (Protocol Version 2.0)

MultiSELECt

A European **Multi**center **S**tudy on the **E**ffect of **L**ipoprotein(a) **E**limination by Lipoprotein Apheresis on **C**ardiovascular ou**t**comes



mit Genehmigung der Diamed Medizintechnik GmbH

A prospective, multicenter, multinational, two-arm matched-pair cohort study

Primary objective

To demonstrate the clinical benefit of Lp(a) reduction using lipoprotein apheresis on the composite endpoint of myocardial infarction, PCI, CABG, fatal and nonfatal stroke, transient ischemic attack, interventional or surgical revascularization of peripheral arteries and death from cardiovascular disease.

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Inclusion Criteria

- Age 18-70
- Male or female
- Written informed consent
- Lipoprotein(a) ≥ 60 mg/dL, or ≥ 120 nmol/L using an alternative laboratory method
- Corrected Low-density lipoprotein cholesterol < 100mg/dl (2.6mmol/l) during 3 months prior to study enrolment
- Established cardiovascular disease with disease progression as indicated by one major cardiovascular event, which might be either myocardial infarction, PCI, CABG, stroke or revascularization of peripheral arteries using PTA, stenting or bypass surgery (with or without subsequent cardiovascular events/interventions) despite adequately controlled cardiovascular risk factors* occuring within the last 2 years prior to enrolment

  (* Hypertension, Diabetes, tobacco consumption, LDL Cholesterol)
- Platelet aggregation inhibitors or systemic anticoagulation according to cardiologic indication
- Positive recommendation by the central Trial Expert Committee

Exclusion Criteria

- Previous lipoprotein apheresis therapy
- Triglyceride concentrations ≥ 250mg/dL (2.8mmol/l)
- Known homozygous or compound heterozygous familial hypercholesterolemia
- Known type III hyperlipoproteinemia
- Pregnancy, breast feeding
- Active smoking, defined as any inhaled tobacco consumption with in the last 3 months
- Uncontrolled hypertension (>160/90 mmHg)
- Active malignant disease
- Planned major surgical procedure
- Current participation in an interventional trial
- Contraindication for apheresis therapy (e.g. necessity of ACE inhibitor therapy)
- CKD stages IV and V
- Diabetes mellitus

Trial duration

At least 2 years follow-up and at least 60 events in control subjects

ClinicalTrials.cov Identifier: NCT02791802

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