

**KURZPROTOKOLL**  
**CTQJ230A12301**

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| <b>Öffentlicher Titel</b>                        | Phase III Studie zur Senkung von Lipoprotein (a) bei kardiovaskulären Erkrankungen                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b>Wissenschaftl. Titel</b>                      | A randomized double-blind, placebo-controlled, multicenter trial assessing the impact of lipoprotein (a) lowering with TQJ230 on major cardiovascular events in patients with established cardiovascular disease                                                                                                                                                                                                                                                                                                               |
| <b>Kurztitel</b>                                 | CTQJ230A12301                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Studienart</b>                                | multizentrisch, prospektiv, Therapiestudie, randomisiert, Pharma-Studie, zweiarmig                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b>Studienphase</b>                              | Phase III                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Erkrankung</b>                                | Herz und Kreislauf: sonstige<br>Drüsen/Hormone/Stoffwechsel: Stoffwechselstörungen<br>Gefäße: Arterienverkalkung (Atherosklerose)                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Einschlusskriterien</b>                       | <ul style="list-style-type: none"><li>- Lp(a) <math>\geq</math> 70 mg/dL at the screening visit, measured at the Central laboratory</li><li>- Myocardial infarction: <math>\geq</math> 3 months from screening and randomization to <math>\leq</math> 10 years prior to the screening visit</li><li>- Ischemic stroke: <math>\geq</math> 3 months from screening and randomization to <math>\leq</math> 10 years prior to the screening visit</li><li>- Clinically significant symptomatic peripheral artery disease</li></ul> |
| <b>Ausschlusskriterien</b>                       | <ul style="list-style-type: none"><li>- Uncontrolled hypertension</li><li>- Heart failure New York Heart Association (NYHA) class IV</li><li>- History of malignancy of any organ system</li><li>- History of hemorrhagic stroke or other major bleeding</li><li>- Platelet count <math>\leq</math> LLN</li><li>- Active liver disease or hepatic dysfunction</li><li>- Significant kidney disease</li><li>- Pregnant or nursing women</li></ul>                                                                               |
| <b>Alter</b>                                     | 18 - 80 Jahre                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Sponsor</b>                                   | Novartis Pharma                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Registrierung in anderen Studienregistern</b> | EudraCT 2019-001076-11<br>ClinicalTrials.gov NCT04023552 (primäres Register)                                                                                                                                                                                                                                                                                                                                                                                                                                                   |