# Clinical trials of PCSK9 Inhibitors for cardiovascular prevention in all type of patients

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## 1 PCSK9 Inhibitor

| Trial | Treatments | Patients | Trials design and methods |
|---|---|---|---|
| **alirocumab vs** | | | |
| CHOICE I *ongoing*<br>[NCT01926782]<br>n=NA | - | - | |
| CHOICE II *ongoing*<br>[NCT02023879]<br>n=NA | - | - | |
| NCT01288469 *ongoing*<br>[NCT01288469]<br>n=NA | - | - | |
| ODYSSEY OUTCOMES<br>*ongoing*<br>[NCT01663402]<br>n=NA | - | - | |
| **evolocumab vs** | | | |
| Mendel 1 , 2012<br>[NCT01375777]<br>n=NA<br>follow-up: | - | - | |
| MENDEl 2<br>[NCT01763827]<br>n=NA | - | - | |
| YUKAWA-1 , 2014<br>n=NA<br>follow-up: | - | - | |
| **alirocumab vs ezetimibe (on top statin)** | | | |
| ODYSSEY OPTIONS I<br>n=NA<br>follow-up: 24 wk | Alirocumab 75 mg with potential up-titration to 150 mg Q2W<br>versus<br>Ezetimibe 10 mg | high-cardiovascular-risk patients with hypercholesterolemia not adequately controlled with atorvastatin (20 or 40 mg) or rosuvastatin (10 or 20 mg) | |
| ODYSSEY OPTIONS II<br>n=NA<br>follow-up: 24 wk | Alirocumab 75 mg with potential up-titration to 150 mg Q2W<br>versus<br>Ezetimibe 10 mg | high-cardiovascular-risk patients with hypercholesterolemia not adequately controlled with atorvastatin (20 or 40 mg) or rosuvastatin (10 or 20 mg) | |
| **alirocumab vs ezetimibe alone** | | | |

continued...

| Trial | Treatments | Patients | Trials design and methods |
|---|---|---|---|
| ODYSSEY MONO<br>[NCT01644474]<br>n=NA<br>follow-up: 24 wk | Alirocumab 75 mg Q2W<br>versus<br>Ezetimibe 10 mg | hypercholesterolemic patients at moderate cardiovascular risk not receiving statins or other lipid-lowering therapy | double-blind |
| **evolocumab vs ezetimibe alone** | | | |
| GAUSS 2<br>[NCT01763905]<br>n=102/205<br>follow-up: | evolocumab 140 mg every two weeks (Q2W) or evolocumab 420 mg once monthly (QM)<br>versus<br>ezetimibe 10 mg | patients with statin intolerance | |
| **bococizumab vs placebo** | | | |
| SPIRE-1 *ongoing*<br>[NCT01975376]<br>n=NA<br>follow-up: | Bococizumab<br>versus<br>placebo | high risk subjects who are receiving background lipid lowering therapy and have cholesterol laboratory values of LDL-C >/= 70 mg/dL (1.8 mmol/L) and <100 mg/dL (2.6 mmol/L) or non-HDL-C >/= 100 mg /dl (2.6 mmol/L) and <130 mg/dL (3.4 mmol/L). | double-blind |
| SPIRE-2 *ongoing*<br>[NCT01975389]<br>n=NA<br>follow-up: | bococizumab<br>versus<br>Placebo | high risk subjects who are receiving background lipid lowering therapy and have cholesterol laboratory values of LDL-C >/= 100 mg/dL (2.6 mmol/L) or non-HDL-C >/=130 mg/dL (3.4 mmol/L). | double-blind |
| SPIRE-FH *ongoing*<br>[NCT01968980]<br>n=NA<br>follow-up: | - | subjects with heterozygous familial hypercholesterolemia receiving highly effective statins | double-blind<br>US |
| SPIRE-HR *ongoing*<br>[NCT01968954]<br>n=NA<br>follow-up: | Bococizumab<br>versus<br>Placebo | subjects with high cholesterol receiving highly effective statins | double-blind<br>US |
| SPIRE-LDL *ongoing*<br>[NCT01968967]<br>n=NA<br>follow-up: | - | subjects with high cholesterol receiving highly effective statins | double-blind<br>US |
| SPIRE-LL *ongoing*<br>[NCT02100514]<br>n=NA<br>follow-up: | - | subjects with hyperlipidemia receiving background statin therapy | double-blind<br>US |
| SPIRE-SI *ongoing*<br>[NCT02135029]<br>n=NA<br>follow-up: | Bococizumab<br>versus<br>Placebo | - | double-blind |
| **evolocumab vs placebo** | | | |

continued...

| Trial | Treatments | Patients | Trials design and methods |
|---|---|---|---|
| GAUSS 1 , 2012<br>[NCT01375764]<br>n=95/32<br>follow-up: | - | statin-intolerant patients | |
| **alirocumab vs placebo (on top statins)** | | | |
| ODYSSEY Alternative<br>[NCT01709513]<br>n=NA<br>follow-up: 65279;24 wk | Alirocumab 75 mg with potential up-titration to 150 mg Q2W<br>versus<br>Ezetimibe 10 mg | statin-intolerant patients | double-blind |
| ODYSSEY COMBO<br>[NCT01644175]<br>n=NA<br>follow-up: 52 wk | Alirocumab 75 mg with potential up-titration to 150 mg Q2W<br>versus<br>Placebo | high cardiovascular risk patients on maximally tolerated statin therapy | double-blind |
| ODYSSEY COMBO II<br>[NCT01644188]<br>n=NA<br>follow-up: 104 wk | Alirocumab 75 mg with potential up-titration to 150 mg Q2W<br>versus<br>Ezetimibe 10 mg | high cardiovascular risk patients with inadequately controlled hypercholesterolaemia on maximally tolerated doses of statins | double-blind |
| ODYSSEY FH 1<br>[NCT01623115]<br>n=NA<br>follow-up: 78 wk | Alirocumab 75 mg with potential up-titration to 150 mg Q2W<br>versus<br>Placebo | patients with heterozygous familial hypercholesterolemia not adequately controlled with current lipid-lowering therapy | double-blind |
| ODYSSEY FH 2<br>[NCT01709500]<br>n=NA<br>follow-up: 78 wk | Alirocumab 75 mg with potential up-titration to 150 mg Q2W<br>versus<br>Placebo | patients with heterozygous familial hypercholesterolemia not adequately controlled with current lipid-lowering therapy | double blind |
| ODYSSEY HIGH FH<br>[NCT01617655]<br>n=NA<br>follow-up: 5278 wk | Alirocumab 150 mg Q2W<br>versus<br>Placebo | patients with heterozygous familial hypercholesterolemia not adequately controlled with current lipid-lowering therapy | |
| ODYSSEY Long-Term , 2015<br>[NCT01507831]<br>n=1553/788<br>follow-up: 78 wk | alirocumab 150 mg as a 1-ml subcutaneous injection every 2 weeks for 78 weeks.<br>versus<br>placebo | patients at high risk for cardiovascular events who had LDL cholesterol levels of 70 mg per deciliter (1.8 mmol per liter) or more and were receiving treatment with statins at the maximum tolerated dose (the highest dose associated with an acceptable side-effect profile), with or without other lipid-lowering therapy | |
| **evolocumab vs placebo (on top statins)** | | | |
| DESCARTES , 2014<br>[NCT01516879]<br>n=599/302<br>follow-up: 52 weeks | evolocumab (420 mg) every 4 weeks<br>versus<br>placebo | - | |
| FOURIER , 2017<br>[NCT01764633]<br>n=NA<br>follow-up: 2.2 years | evolocumab (either 140 mg every 2 weeks or 420 mg monthly)<br>versus<br>placebo | patients with atherosclerotic cardiovascular disease and LDL cholesterol levels of 70 mg per deciliter (1.8 mmol per liter) or higher who were receiving statin therapy | Parallel groups<br>double-blind |

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| Trial | Treatments | Patients | Trials design and methods |
|---|---|---|---|
| LAPLACE 2 , 2014<br>[NCT01763866]<br>n=1117/558<br>follow-up: | evolucumab + statin<br>versus<br>placebo + statin | - | |
| LAPLACE-TIMI 57<br>[NCT01380730]<br>n=NA<br>follow-up: | subcutaneous injections of AMG 145 70 mg, 105 mg, or 140 mg,<br>versus<br>placebo | - | |
| RUTHERFORD-1<br>[NCT01375751]<br>n=111/56<br>follow-up: | AMG 145 350 mg, AMG 145 420 mg<br>versus<br>placebo | heterozygous familial hypercholesterolemia patients | |
| RUTHERFORD-2 , 2015<br>[NCT01763918]<br>n=220/109<br>follow-up: | subcutaneous evolocumab 140 mg every 2 weeks, evolocumab 420 mg monthly<br>versus<br>placebo | heterozygous familial hypercholesterolaemia | |

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# 2 About TrialResults-center.org

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The TrialResults-center database provides a unique view of the treatment efficacy based on all data provided directly from clinical trial results, offering a valuable alternative to personal bibliographic search, published meta-analysis, etc. Furthermore, it would allow comparing easily the various concurrent therapeutic for the same clinical condition.

Rigorous meta-analysis method is used to populate TrialResults-center: widespread search of published and non published trials, study selection using pre-specified criteria, data extraction using standard form.

TrialResults-center is continually updated on a weekly basis. We continually search all new results (whatever their publication channel) and these news results are immediately added to the database with a maximum of 1 week.

TrialResults-center is non-profit and self-funded.