TrialsConnect — SPIRE 1

Study Summary

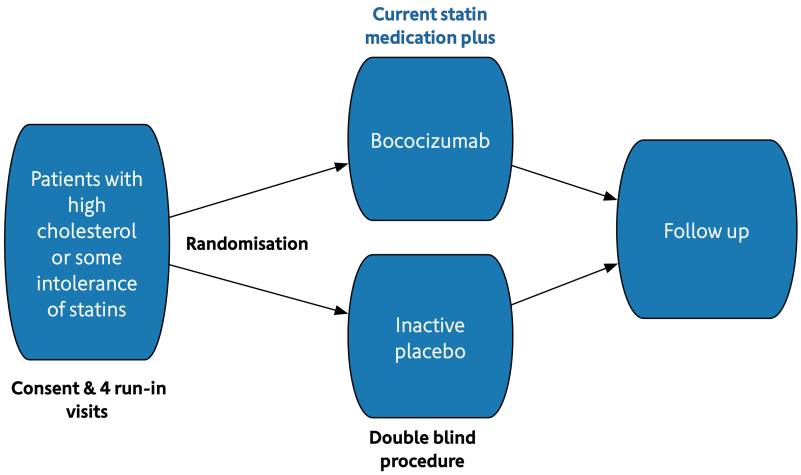
One of two multi-national Phase 3 Studies

Studies of PCSK9 Inhibition and the Reduction in vascular Events

This study, funded by Pfizer Inc. , was to determine the effects of *Bococizumab*, a new drug by comparing it with an inactive placebo. The aim was find out how safe and effective *Bococizumab* is in reducing the risk of heart attack or stroke when added to current or other cholesterol treatments.

Doctors may recommend aiming to get a cholesterol measurement ('LDL-C') under 70 mg/dL if you are at risk of having a heart attack or stroke. **SPIRE 1** recruited patients with a cholesterol reading higher than 70 mg/dL or who were partially statin intolerant.

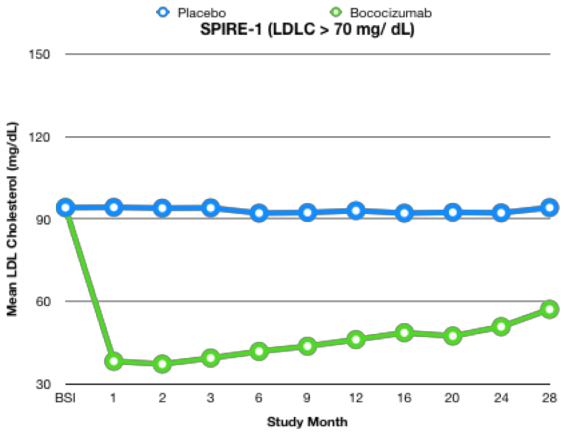
SPIRE 1



Bococizumab is a 'humanized monoclonal antibody' that reduces levels of low-density cholesterol by reducing the effect of the gene (PCSK9) which controls cholesterol levels in the blood . In **SPIRE 1** the purpose was to find out how well *Bocoizumab* works in patients who are at a lower risk for cardiovascular events but still have higher than desirable LDL cholesterol.

Bococizumab is not being fully 'humanised' — up to 10% of its genetic sequence could still be unrelated to humans. This means that patients who were on the drug long-term might develop resistance (antibodies). A little over half the patients on the drug developed antibodies, this resulted in the drug being pulled earlier then intended by the sponsor.

SPIRE 1 proved that for patients who are at lower risk the drug, Bococizumab, did not lower the risk of major cardiovascular events. **SPIRE 1** was stopped early because another study showed that the drug became less effective — over time the patients' cholesterol went back towards normal.



Information from summary prepared by *The New England Journal of Medicine*: https://www.nejm.org/doi/full/10.1056/NEJMoa1701488

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TrialsConnect — SPIRE 2

Study Summary

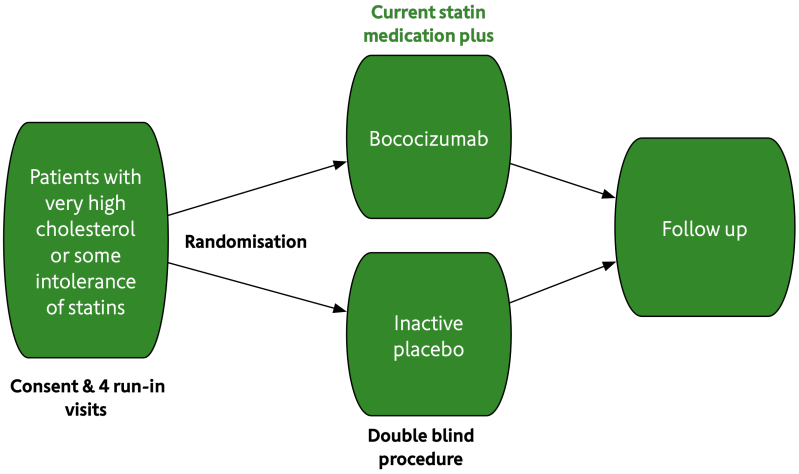
One of two multi-national Phase 3 Studies

Studies of PCSK9 Inhibition and the Reduction in vascular Events

This study, funded by Pfizer Inc. , was to determine the effects of *Bococizumab*, a new drug by comparing it with an inactive placebo. The aim was find out how safe and effective *Bococizumab* is in reducing the risk of heart attack or stroke when added to current or other cholesterol treatments with a high risk.

Doctors may recommend aiming to get a cholesterol measurement ('LDL-C') under 70 mg/dL if you are at risk of having a heart attack or stroke. **SPIRE 2** recruited 'high risk' patients with a cholesterol reading higher than 100 mg/dL or who were partially statin intolerant.

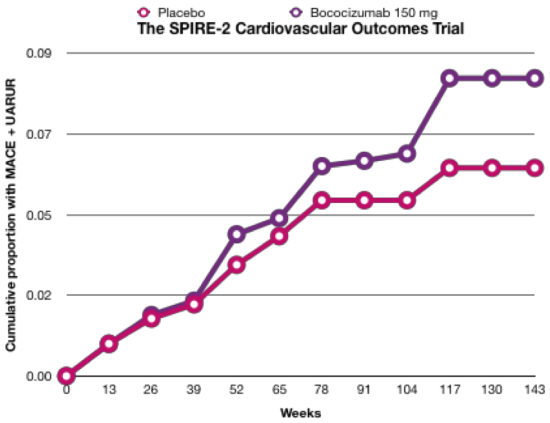
SPIRE 2



Bococizumab is a 'humanized monoclonal antibody' that reduces levels of low-density cholesterol by reducing the effect of the gene (PCSK9) which controls cholesterol levels in the blood . In **SPIRE 2** the purpose was to find out how well *Bocoizumab* works in patients who are at a higher risk for cardiovascular events than in **SPIRE 1**.

Bococizumab is not being fully 'humanised' — up to 10% of its genetic sequence could still be unrelated to humans. This means that patients who were on the drug long-term might develop resistance (antibodies). A little over half the patients on the drug developed antibodies, this resulted in the drug being pulled earlier then intended by the sponsor.

SPIRE 2 proved that for patients who are at higher risk the drug, *Bococizumab*, did lower the risk of major cardiovascular events (heart attacks and strokes) by approximately 20%. But overtime the patient's cholesterol began to rise just as in **SPIRE 1**, so the drug was abandoned.



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