InclisiranによりLDLコレステロールが58%低下 (Late breaking Science I)

ORION試験: コレステロール低下治験薬はLDLコレステロール低下に有効である

ORION: Experimental cholesterol-lowering drug effective at lowering LDL-cholesterol

コレステロール低下治験薬inclisiranの年2回の注射は、既に最大用量のスタチン製剤を内服している患者の低比重リポ蛋白(LDL)コレステロール低下に有効であるとのORION-10試験のデータが American Heart Association's Scientific Sessions 2019で発表された。Inclisiranは初回投与から3か月後、その後は6か月毎に投与され、その結果510日目にはLDLコレステロールが58%低下し、90~540日の間の時間平均プラセボ補正LDLコレステロールは56%低下した。AHAで発表された他の第3相試験(ORION-9)では、家族性高コレステロール血症患者においてinclisiranはLDLコレステロール値を50%低下させた。

Full Text

Twice-yearly injections of an experimental cholesterol-lowering drug, inclisiran, were effective at reducing low-density lipoprotein (LDL) cholesterol in patients already taking the maximum dose of statin drugs, according to data of the ORION-10 trial presented in a Late Breaking Science session at the American Heart Association's (AHA) Scientific Sessions 2010

"Maintaining low LDL over a sustained period is essential to reduce the risk of heart attacks and stroke," says R. Scott Wright, M.D., a Mayo Clinic cardiologist and principal investigator of ORION-10 trial.

ORION-10, a phase 3 placebo-controlled, double-blind, randomized study at 145 U.S. sites, enrolled 1,561 participants with established atherosclerotic cardiovascular disease and elevated LDL (greater than 70 milligrams per deciliters), despite maximum tolerated oral statin therapies. Participants received inclisiran or placebo by subcutaneous injections at baseline, and then at three months and every six months thereafter.

Inclisiran, developed by The Medicines Company, is a siRNA (small interfering RNA) drug and the only cholesterol-lowering medication in its class. The medication mimics a gene variant and prevents production of the protein PCSK9, which in turn lowers LDL.

Inclisiran dosed initially, and then again at three months and every six months thereafter, resulted in placebo-adjusted LDL reductions of 58% at day 510 and demonstrated time-averaged, placebo-adjusted LDL reductions of 56% from days 90 through 540.

"The data show that inclisiran dosed twice-yearly achieved durable and potent LDL reductions with an excellent safety profile, and no treatment-related liver or kidney side effects," Dr. Wright says. "Twice-yearly administration by a health care professional coincides with typical patient visits, which can help with medication adherence."

In another phase 3 trial also presented at AHA (ORION-9) inclisiran reduced LDL levels by 50% in patients with familial hypercholesterolemia.

Dr. Wright has received consulting fees from The Medicines Company.

AHA 2019 特集

トピックス一覧

[News01]

うつ病の重症度が心疾患リスクを増大させる

[News02]

女性のストレスに対する反応が心血管リスクを増大させる

[News03

週末の突然の心停止は死亡率が高い

[ΝρινςΩ4

早期閉経は複数の心疾患リスクを増大させる可能性がある

News051

大麻は若年者の脳卒中と関連がある

[News06]

心疾患とがんリスクは関連する可能性がある

[News07]

インターベンション治療は薬物療法と大して変わらない

News081

慢性腎臓病患者において侵襲的治療戦略により得るものはない

[News09]

ダバグリフロジンの有益性が糖尿病を合併しない心不全 患者に拡大される

[News10]

心臓ポンプは一部の患者において合併症を引き起こす

[News11]

10代の先天性心疾患患者が運動耐容能を改善する

[News12]

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