

## VYTUL

ACTRN12606000374561

---

<b>Status</b>	RECRUITING
<b>Phase</b>	Phase 4
<b>Sponsor</b>	Merck Sharp & Dohme Australia & Schering-Plough Pty. Limited
<b>Enrollment</b>	550 participants

### Plain Language Summary

---

This study is comparing two different approaches to lowering 'bad' cholesterol (LDL cholesterol) in people whose levels are too high despite already being on a common cholesterol medication called atorvastatin 40mg. The two options being compared are: switching to a combination pill called Vytorin (which contains two cholesterol-lowering drugs together) or increasing the dose of atorvastatin alone. The study aims to see which approach is more effective at bringing cholesterol down to safe target levels in people at high risk of heart disease.

You may be eligible if:

- You are 18 years of age or older
- You have been taking atorvastatin 40mg daily for at least 3 months
- You have existing coronary heart disease with cholesterol above 4.0 mmol/L, OR you have diabetes with cholesterol above certain levels
- You are otherwise in good health with no significant other diseases

You may NOT be eligible if:

- Your diabetes is uncontrolled (HbA1c above 9%)
- You have elevated liver enzymes or creatine kinase (muscle enzyme) in blood tests
- You have high triglycerides (blood fat) above 4.5 mmol/L
- You have significant kidney problems
- You have a drug or alcohol dependency in the last 6 months
- You are pregnant, breastfeeding, or a woman of childbearing age not using reliable contraception
- You have taken certain medications such as fibrates, niacin, or antifungals in the past 5 weeks

Talk to your doctor about whether this trial might be right for you.

### Key Eligibility Criteria

---

#### Inclusion (1)

- Capable of and willing to sign written informed consent- Has been treated for at least the last 3 months with a daily dose of atorvastatin 40 mg- Existing coronary heart disease and has cholesterol > 4.0 mmol/L measured at Visit 1 OR diabetes mellitus and has measured at Visit 1 • cholesterol > 6.5 mmol/L OR • cholesterol > 5.5 mmol/L and HDL < 1 mmol/L- Free of any clinically significant diseases, other than hyperlipidaemia, that would interfere with study evaluations and willing and able to attend all study visits.

#### Exclusion (1)

- Uncontrolled diabetes, defined by a measured HbA1c > 9% as measured at Visit 1-Has alanine aminotransferase (ALT) > 1.5 times Upper Limit of Normal (ULN) as measured at Visit 1- Has aspartate aminotransferase (AST) > 1.5 times ULN as measured at Visit 1-Has creatine kinase (CK) > 1.5 times ULN as measured at Visit 1- Has triglycerides (TG) > 4.5 mmol/L as measured at Visit 1- Has evidence of renal impairment with a serum creatinine > 200 µmol/L as measured at Visit 1- Has known drug or alcohol dependency within 6 months prior to Visit 1-A woman receiving hormonal therapy, including hormone replacement, anyestrogen — antagonist/agonist, or oral contraceptives, who have not been maintained on a stable dose and regimen for at least 8 weeks and are willing to continue the same regimen for the duration of the study.- A woman of childbearing potential (includes women who are less than 1 year postmenopausal or not surgically sterile) not using an acceptable method of birth control (e.g., hormonal

DISCLAIMER: This document is for informational purposes only and does not constitute medical advice. Always consult your healthcare provider before enrolling in any clinical trial. Information may not be up to date — verify details at [anzctr.org.au](https://www.anzctr.org.au). Generated by [ClinicalTrialsFinder.org](https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12606000374561).

contraceptive, medically prescribed IUD, condomin combination with spermicide)- Women who are pregnant or breast feeding- Any condition or situation which, in the opinion of the investigator, might pose arisk to the subject or interfere with participation in the studyProhibited Medication for the Duration of the Study- Medications taken within 5 weeks prior to Visit 1 (Screening Visit) including: macrolide antibiotics, azole antifungals, fibric acid derivatives, niacin- Other medication as listed in the product information sheets for ezetimibe/simvastatin and atorvastatin.

## Locations (1 total)

---

Australia