

## Statins and Primary Prevention of Cardiovascular Disease

**Population:** Men and women aged 18 or above without previous CVD (Trials conducted from 1994 to 2008 in Japan, USA, Europe, South American, Israel, South Africa and Russia. Fourteen trials recruited patients with specific conditions: nine recruited participants with raised lipids, four with diabetes, two with hypertension and one with microalbuminuria.)

**Intervention:** Statin (statin 10 mg to 40 mg per day; atorvastatin 10 mg to 80 mg per day; fluvastatin 40 mg to 80 mg per day; lovastatin 20 mg to 40 mg per day; two rosuvastatin 20 mg to 40 mg per day; two simvastatin 20 mg to 40 mg per day)

**Comparator:** Placebo

Outcome 1 to 5.3 years	Study results and measurements	Certainty in effect estimates (Quality of evidence)	Absolute effect estimates		Summary
			Placebo	Statin	
Total Mortality	Relative risk: 0.86 (CI 95% 0.79 - 0.94) Based on data from 48060 patients in 13 studies	High Quality of Evidence – due to low risk of bias	<b>52 per 1000</b>  <b>Difference: 7 fewer per 1000</b> (CI 95% 10 fewer - 3 fewer)	<b>45 per 1000</b>	Statins decreases total mortality
Total Number of CHD Events	Relative risk: 0.73 (CI 95% 0.67 - 0.8) Based on data from 48049 patients in 14 studies	High Quality of Evidence – due to low risk of bias	<b>47 per 1000</b>  <b>Difference: 13 fewer per 1000</b> (CI 95% 16 fewer - 9 fewer)	<b>34 per 1000</b>	Statins decreases the risk for CHD events
Number of Fatal CHD Events	Relative risk: 0.82 (CI 95% 0.7 - 0.96) Based on data from 46094 patients in 10 studies	High Quality of Evidence – due to low risk of bias	<b>13 per 1000</b>  <b>Difference: 2 fewer per 1000</b> (CI 95% 4 fewer - 1 fewer)	<b>11 per 1000</b>	Statins decreases the risk for fatal CHD events
Number of Non-fatal CHD Events	Relative risk: 0.67 (CI 95% 0.59 - 0.76) Based on data from 40977 patients in 11 studies	High Quality of Evidence – due to low risk of bias	<b>29 per 1000</b>  <b>Difference: 10 fewer per 1000</b> (CI 95% 12 fewer - 7 fewer)	<b>19 per 1000</b>	Statins decreases the risk for non- fatal CHD events
Total Number of CVD Events	Relative risk: 0.75 (CI 95% 0.7 - 0.81) Based on data from 23805 patients in 9 studies	High Quality of Evidence – due to low risk of bias	<b>122 per 1000</b>  <b>Difference: 31 fewer per 1000</b> (CI 95% 37 fewer - 23 fewer)	<b>92 per 1000</b>	Statins decreases the risk for CVD events

Number of Fatal CVD Events	Relative risk: 0.83 (CI 95% 0.72 - 0.96) Based on data from 34012 patients in 5 studies	High Quality of Evidence – due to low risk of bias	<b>21</b> <b>per 1000</b> <b>Difference: 4 fewer per 1000</b> (CI 95% 6 fewer - 1 fewer)	<b>17</b> <b>per 1000</b> <b>Difference: 4 fewer per 1000</b> (CI 95% 6 fewer - 1 fewer)	Statins decreases the risk for fatal CVD events
Number of Non-fatal CVD Events	Relative risk: 0.77 (CI 95% 0.62 - 0.96) Based on data from 8696 patients in 2 studies	High Quality of Evidence – due to low risk of bias	<b>40</b> <b>per 1000</b> <b>Difference: 9 fewer per 1000</b> (CI 95% 15 fewer - 2 fewer)	<b>31</b> <b>per 1000</b> <b>Difference: 9 fewer per 1000</b> (CI 95% 15 fewer - 2 fewer)	Statins decreases the risk for non-fatal CVD events
Total Number of Stroke Events	Relative risk: 0.78 (CI 95% 0.68 - 0.89) Based on data from 40295 patients in 10 studies	High Quality of Evidence – due to low risk of bias	<b>22</b> <b>per 1000</b> <b>Difference: 5 fewer per 1000</b> (CI 95% 7 fewer - 2 fewer)	<b>17</b> <b>per 1000</b> <b>Difference: 5 fewer per 1000</b> (CI 95% 7 fewer - 2 fewer)	Statins decreases the risk for stroke
Number of Fatal Stroke Events	Relative risk: 0.63 (CI 95% 0.18 - 2.23) Based on data from 27238 patients in 3 studies	High Quality of Evidence – due to low risk of bias	<b>4</b> <b>per 1000</b> <b>Difference: 1 fewer per 1000</b> (CI 95% 3 fewer - 5 more)	<b>3</b> <b>per 1000</b> <b>Difference: 1 fewer per 1000</b> (CI 95% 3 fewer - 5 more)	Statins have little or no effect on the for fatal stroke
Number of Non-fatal Stroke Events	Relative risk: 0.69 (CI 95% 0.58 - 0.83) Based on data from 28097 patients in 5 studies	High Quality of Evidence – due to low risk of bias	<b>20</b> <b>per 1000</b> <b>Difference: 6 fewer per 1000</b> (CI 95% 8 fewer - 3 fewer)	<b>14</b> <b>per 1000</b> <b>Difference: 6 fewer per 1000</b> (CI 95% 8 fewer - 3 fewer)	Statins decreases the risk for non-fatal stroke
Total Number of Fatal and Non-fatal CHD, CVD and Stroke Events	Relative risk: 0.65 (CI 95% 0.58 - 0.73) Based on data from 35254 patients in 4 studies	High Quality of Evidence – due to low risk of bias	<b>38</b> <b>per 1000</b> <b>Difference: 13 fewer per 1000</b> (CI 95% 16 fewer - 10 fewer)	<b>25</b> <b>per 1000</b> <b>Difference: 13 fewer per 1000</b> (CI 95% 16 fewer - 10 fewer)	Statins decreases the risk for fatal and non-fatal CHD, CVD and Stroke
Number of Study Participants who underwent Revascularisation	Relative risk: 0.62 (CI 95% 0.54 - 0.72) Based on data from 42403 patients in 7 studies	High Quality of Evidence – due to low risk of bias	<b>22</b> <b>per 1000</b> <b>Difference: 8 fewer per 1000</b> (CI 95% 10 fewer - 6 fewer)	<b>14</b> <b>per 1000</b> <b>Difference: 8 fewer per 1000</b> (CI 95% 10 fewer - 6 fewer)	Statins decreases revascularisation

#### Adverse Events:

Outcome Timeframe	Study results and measurements	Certainty in effect estimates (Quality of evidence)	Absolute effect estimates Placebo      Statins	Summary
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Number of study participants who had adverse events	Relative risk: 1.0 (CI 95% 0.97 - 1.03) Based on data from 40716 patients in 12 studies	High Quality of Evidence – due to low risk of bias	<b>255 per 1000</b> <b>Difference: 0 fewer per 1000</b> (CI 95% 8 fewer - 8 more)	Statins have little or no effect on adverse events
Number of study participants who stopped treatment due to adverse events	Relative risk: 0.86 (CI 95% 0.65 - 1.12) Based on data from 21642 patients in 9 studies	High Quality of Evidence – due to low risk of bias	<b>92 per 1000</b> <b>80 per 1000</b> <b>Difference: 12 fewer per 1000</b> (CI 95% 30 fewer - 10 more)	Statins have little or no effect on stopping treatment due to adverse events
Number of study participants who were admitted to hospital	Relative risk: 0.74 (CI 95% 0.38 - 1.41) Based on data from 19707 patients in 2 studies	High Quality of Evidence – due to low risk of bias	<b>21 per 1000</b> <b>16 per 1000</b> <b>Difference: 5 fewer per 1000</b> (CI 95% 13 fewer - 9 more)	Statins have little or no effect on hospital admittance
Number of study participants who developed cancer	Relative risk: 1.01 (CI 95% 0.93 - 1.1) Based on data from 38739 patients in 11 studies	High Quality of Evidence – due to low risk of bias	<b>57 per 1000</b> <b>58 per 1000</b> <b>Difference: 1 more per 1000</b> (CI 95% 4 fewer - 6 more)	Statins have little or no effect on cancer
Number of study participants who developed myalgia or muscle pain	Relative risk: 1.03 (CI 95% 0.97 - 1.09) Based on data from 37938 patients in 9 studies	High Quality of Evidence – due to low risk of bias	<b>92 per 1000</b> <b>95 per 1000</b> <b>Difference: 3 more per 1000</b> (CI 95% 3 fewer - 8 more)	Statins have little or no effect on myalgia or muscle pain
Number of study participants who developed rhabdomyolysis	Relative risk: 1.0 (CI 95% 0.23 - 4.38) Based on data from 38468 patients in 6 studies	High Quality of Evidence – due to low risk of bias	<b>0 per 1000</b> <b>0 per 1000</b> <b>Difference: 0 fewer per 1000</b> (CI 95% 0 fewer - 0 fewer)	Statins have little or no effect on rhabdomyolysis
Number of study participants who developed diabetes	Relative risk: 1.18 (CI 95% 1.01 - 1.39) Based on data from 24407 patients in 2 studies	High Quality of Evidence – due to low risk of bias	<b>24 per 1000</b> <b>28 per 1000</b> <b>Difference: 4 more per 1000</b> (CI 95% 0 fewer - 9 more)	Statins increases the risk of developing diabetes
Number of study participants who developed haemorrhagic stroke	Relative risk: 0.97 (CI 95% 0.54 - 1.75) Based on data from 25634 patients in 2 studies	High Quality of Evidence – due to low risk of bias	<b>2 per 1000</b> <b>1 per 1000</b> <b>Difference: 0 fewer per 1000</b> (CI 95% 1 fewer - 1 more)	Statins have little or no effect on haemorrhagic stroke

Number of study participants who had elevated liver enzymes	Relative risk: 1.16 (CI 95% 0.87 - 1.54) Based on data from 40094 patients in 10 studies	High Quality of Evidence – due to low risk of bias	<b>24</b> <b>per 1000</b>  <b>Difference: 4 more per 1000</b> (CI 95% 3 fewer - 13 more)	<b>28</b> <b>per 1000</b>  Statins have little or no effect on elevated liver enzymes
Number of study participants who developed renal disorder	Relative risk: 1.11 (CI 95% 0.99 - 1.26) Based on data from 27804 patients in 4 studies	High Quality of Evidence – due to low risk of bias	<b>37</b> <b>per 1000</b>  <b>Difference: 4 more per 1000</b> (CI 95% 0 fewer - 9 more)	<b>40</b> <b>per 1000</b>  Statins have little or no effect on renal disorders
Number of study participants who developed arthritis	Relative risk: 1.2 (CI 95% 0.82 - 1.75) Based on data from 7586 patients in 2 studies	High Quality of Evidence – due to low risk of bias	<b>47</b> <b>per 1000</b>  <b>Difference: 9 more per 1000</b> (CI 95% 8 fewer - 32 more)	<b>55</b> <b>per 1000</b>  Statins have little or no effect on arthritis

## References

Taylor F, Huffman MD, Macedo AF, Moore TH, Burke M, Davey Smith G, Ward K, Ebrahim S. Statins for the primary prevention of cardiovascular disease. The Cochrane Library. 2013 Jan 1.

## Practical Issues



### Medical routine

How often do I need to take the medication?

Most statins are required to be taken daily. The amount of tablets/capsule per day varies with each class of medication which your doctor should explain to you.



### Adverse effects, interactions and antidote

Are there any side effects from taking a statin?

In general, 255 in 1000 people on a statin may report an adverse event compared to 255 in 1000 people on a placebo. Some specific side effects include:

- Muscle pain (or myalgia): 95 in 1000 people may report muscle pain when on a statin compared to 92 in 1000 on a placebo pill.
- Diabetes: 24 in 1000 people may develop diabetes when on a statin compared to 28 in 1000 on a placebo pill.



### Cost and access

How much does the statin cost?

Prices depend on the specific statin. In Australia:

- Atorvastatin for 30 × 80 mg tablets = \$16.37
- Fluvastatin 30 × 80 mg tablets = \$ 45.59
- Rosuvastatin for 30 × 20 mg tablets = \$18.95
- Simvastatin for 30 × 20 mg = \$12.91