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Record linkage in clinical Trials: an idea whose time has come?

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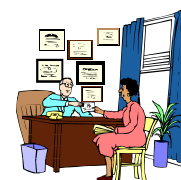
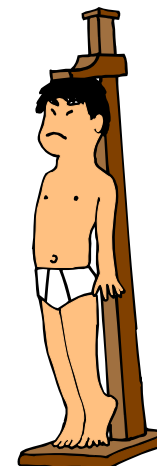
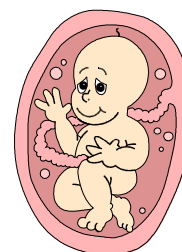


Information transfer: former



From conception to death...

- Mothers ante-natal records
- Maternity
- Neonatal record
- Register birth - NHS number
- Register with GP - CHI
- GP Appointments
- Dental Appointments
- Outpatients
- A&E attendance
- General hospital admission
- Prescribing
- Cancer registration
- Cancer treatment
- Community care
- Death



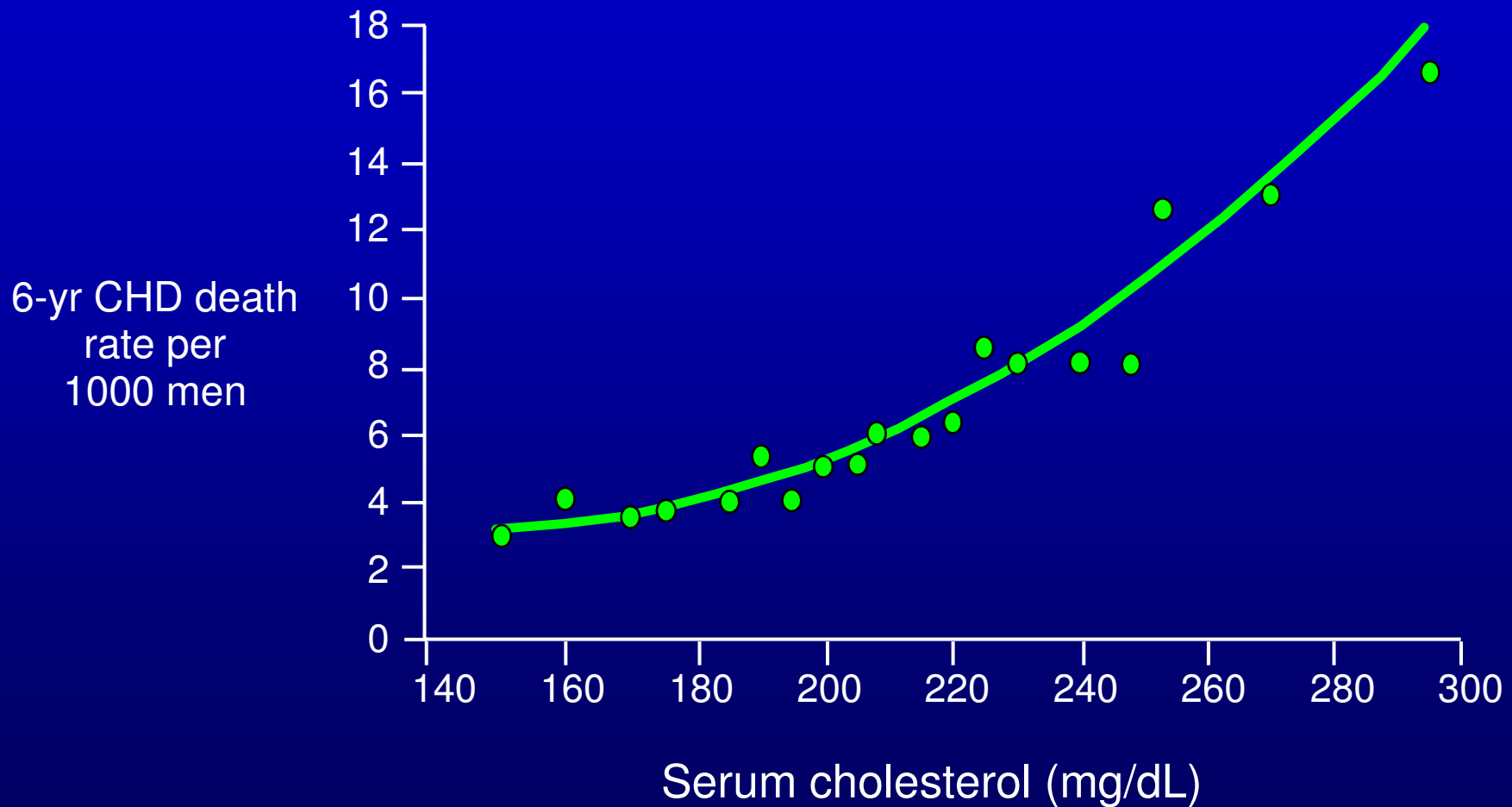


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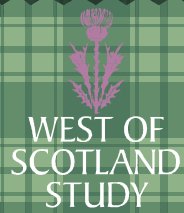
NHS
Greater Glasgow
and Clyde

An example

MRFIT: Age-Adjusted CHD Death Rate and Serum Cholesterol in 361,662 US Men



Martin et al: *Lancet* 1986;2:933-936



West of Scotland Coronary Prevention Study

WOSCOPS

- **Randomised double blind placebo controlled trial of pravastatin (40mg per night) in hypercholesterolaemic men aged 45-64 with no history of myocardial infarction**
- **Recruitment in primary care**

WOSCOPS: numbers



– Screenees

- 81,161

– Visit 2

- 20,914

– Visit 3

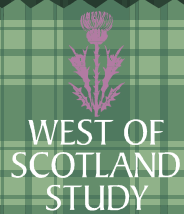
- 13,654

– Randomised

- 6595

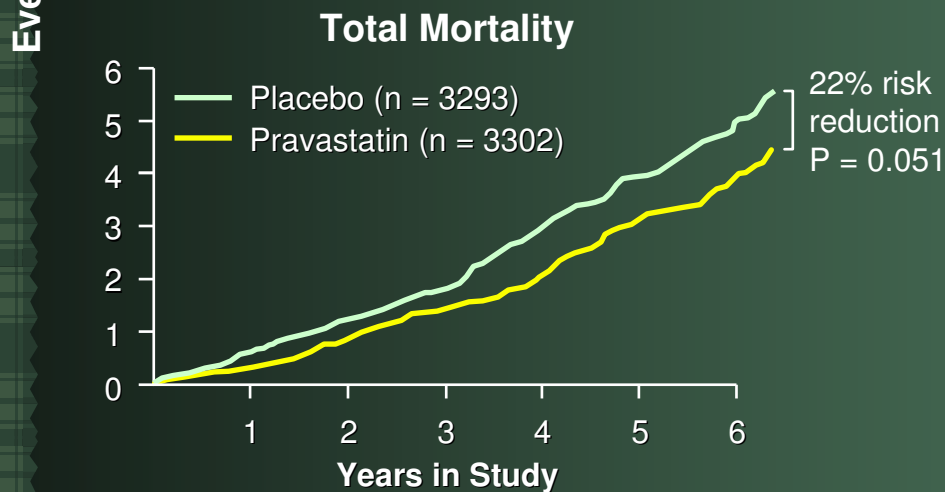
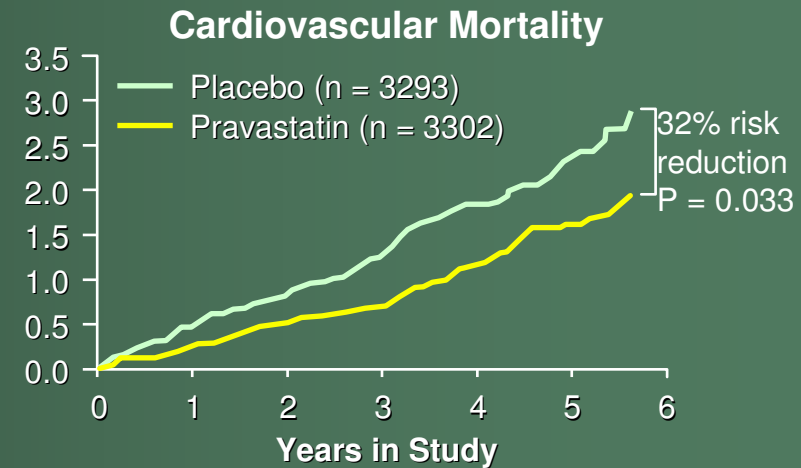
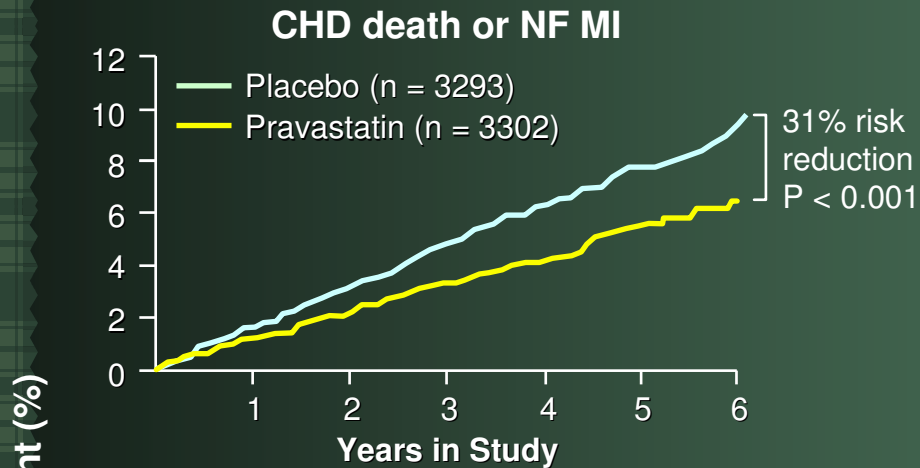
– Follow-up

- 3.5-6.1 years
- Mean 4.9 years
- Total 32,216 years

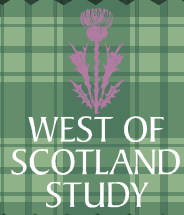


West of Scotland Coronary Prevention Study

WOSCOPS: results (adjudicated)

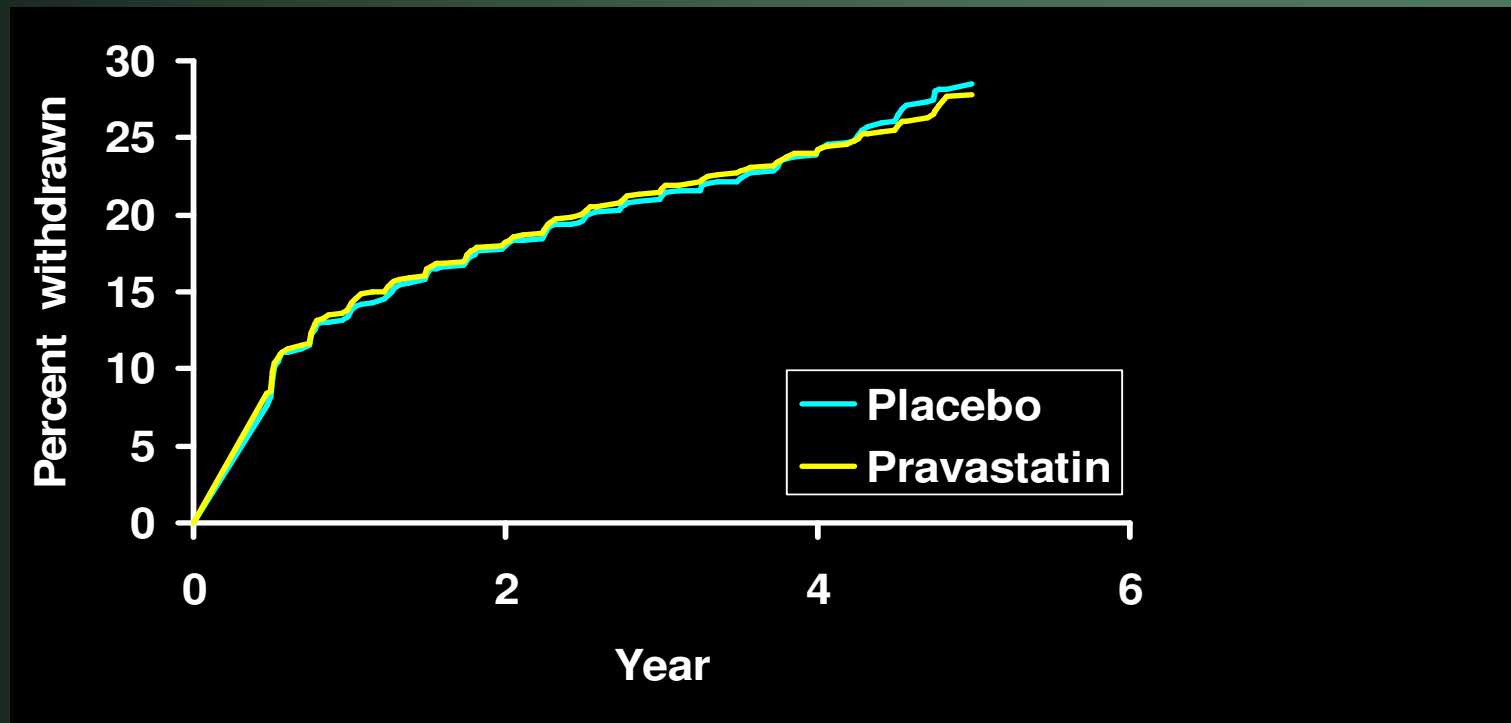


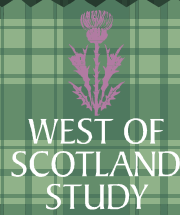
Shepherd et al. N Engl J Med. 1995;333:1301-1307.



West of Scotland Coronary Prevention Study

Withdrawals from study medication

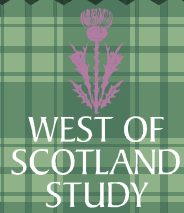




West of Scotland Coronary Prevention Study

Follow-up - design

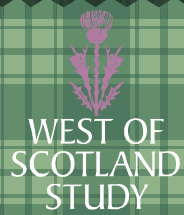
- **Follow-up of cholesterol lowering treatment**
 - Review of GP records at 1, 3, 5 years post-trial
- **Follow-up for events**
 - Electronic linkage to Scottish national datasets
 - Safety
 - non-CV deaths, incident cancers
 - Continuing benefit
 - coronary outcomes, stroke
 - Within-trial events also re-identified electronically for consistency and proof of concept



West of Scotland Coronary Prevention Study

WOSCOPS: follow-up

- **Within-trial follow-up**
 - 3.5 - 6.1 years
 - Mean 4.9 years
- **Total follow-up**
 - Incident cancers
 - 11.8 – 14.4 years
 - Mean 13.2 years
 - Other outcomes
 - 13.3 – 15.9 years
 - Mean 14.7 years



West of Scotland Coronary Prevention Study

WOSCOPS: electronic long-term follow-up

The NEW ENGLAND
JOURNAL *of* MEDICINE

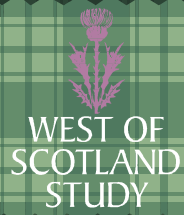
ESTABLISHED IN 1812

OCTOBER 11, 2007

VOL. 357 NO. 15

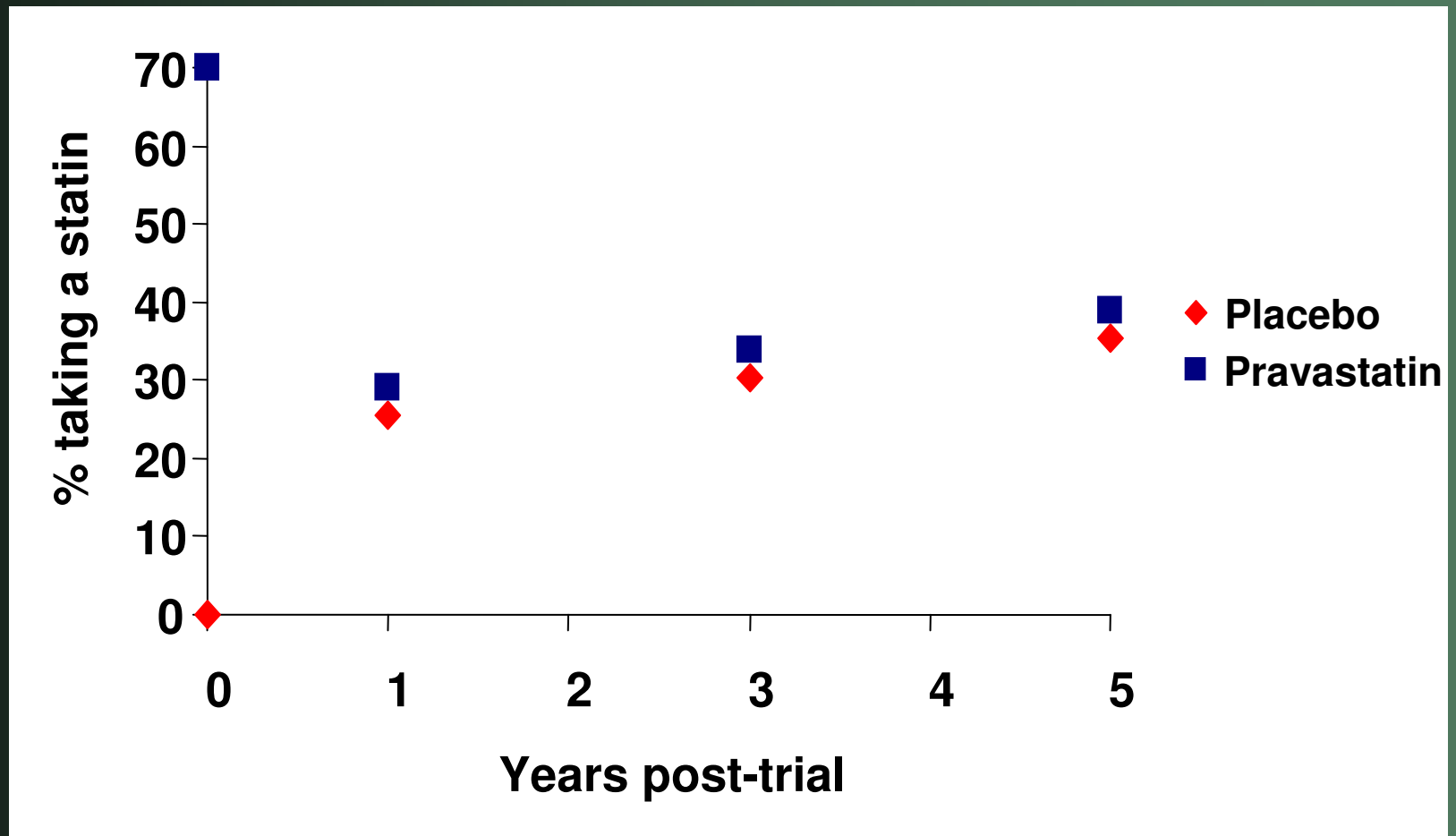
Long-Term Follow-up of the West of Scotland
Coronary Prevention Study

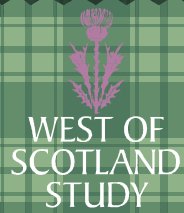
Ian Ford, Ph.D., Heather Murray, M.Sc., Chris J. Packard, D.Sc., James Shepherd, M.D., Peter W. Macfarlane, D.Sc.,
and Stuart M. Cobbe, M.D., for the West of Scotland Coronary Prevention Study Group



West of Scotland Coronary Prevention Study

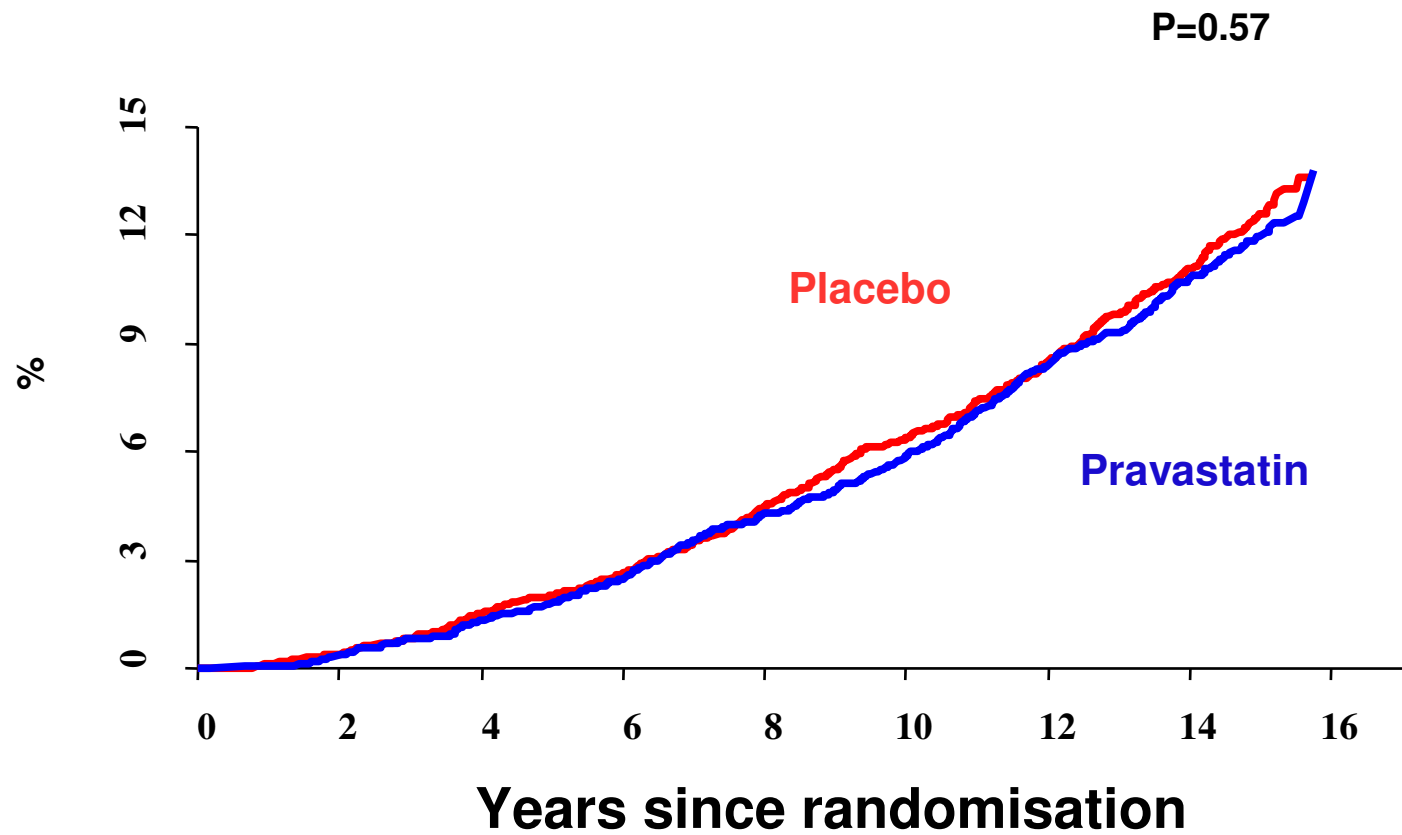
Results: statin treatment post-trial

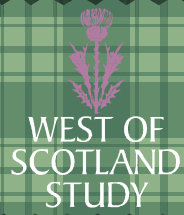




West of Scotland Coronary Prevention Study

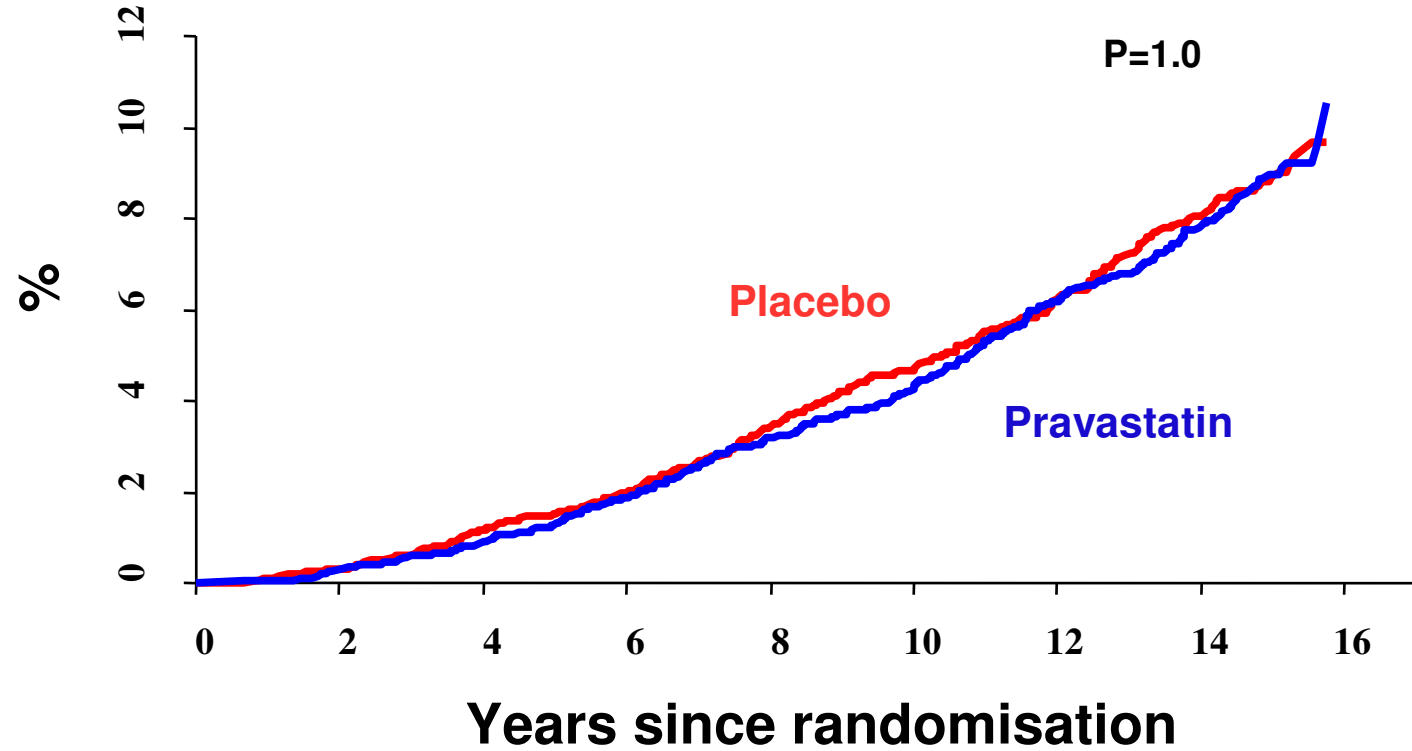
Non-CVD deaths

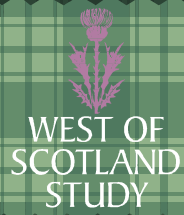




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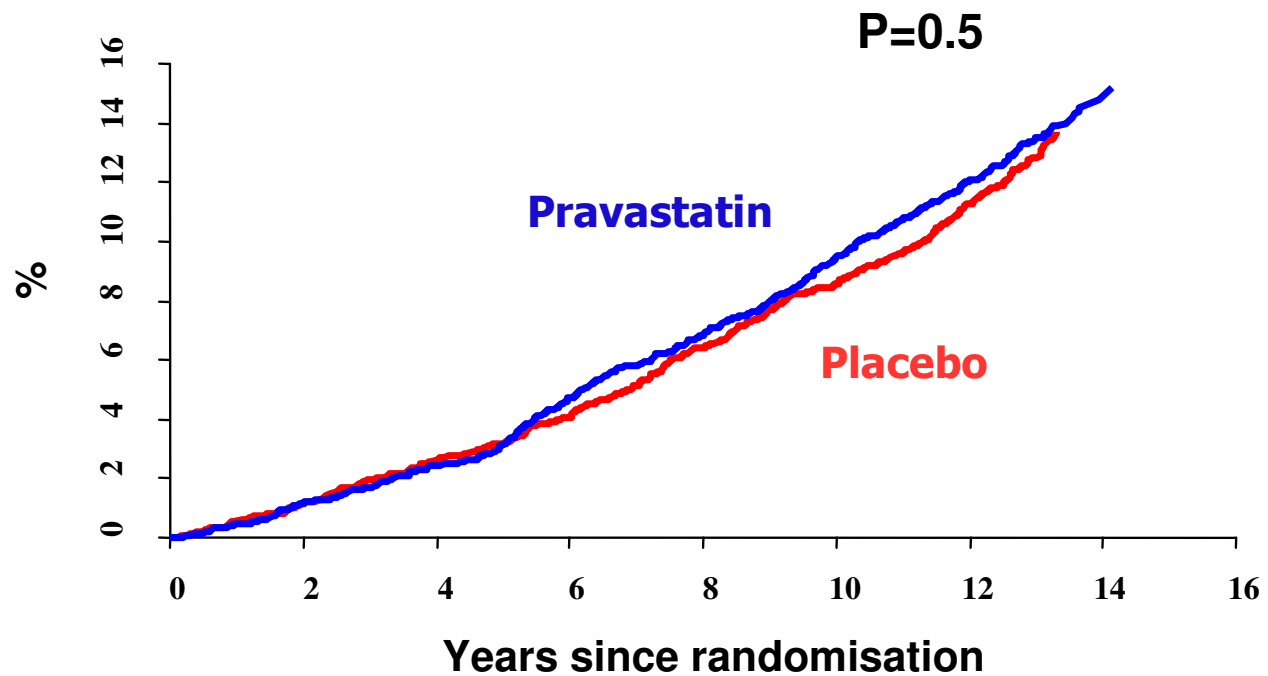
Cancer deaths

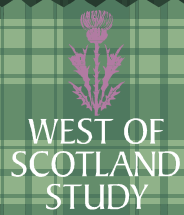




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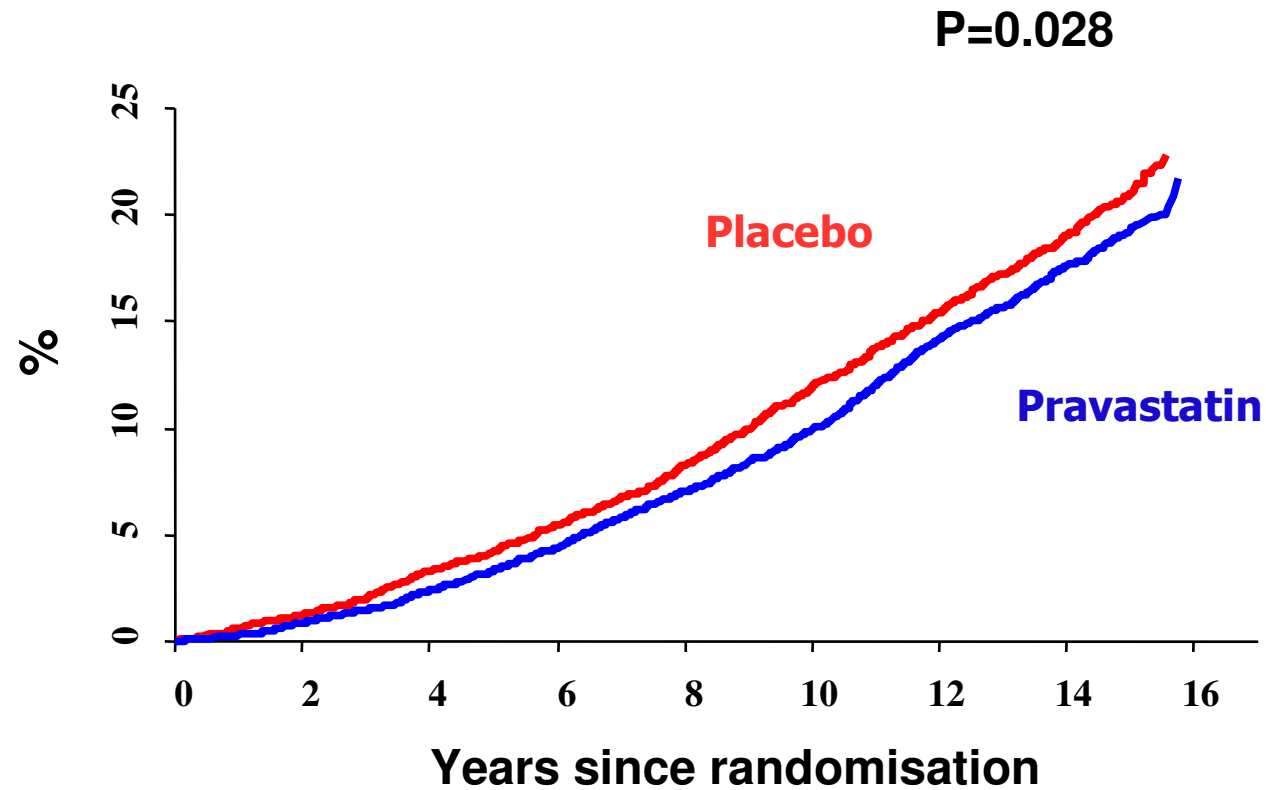
Incident Cancers

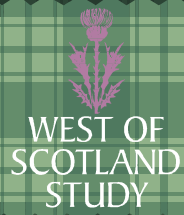




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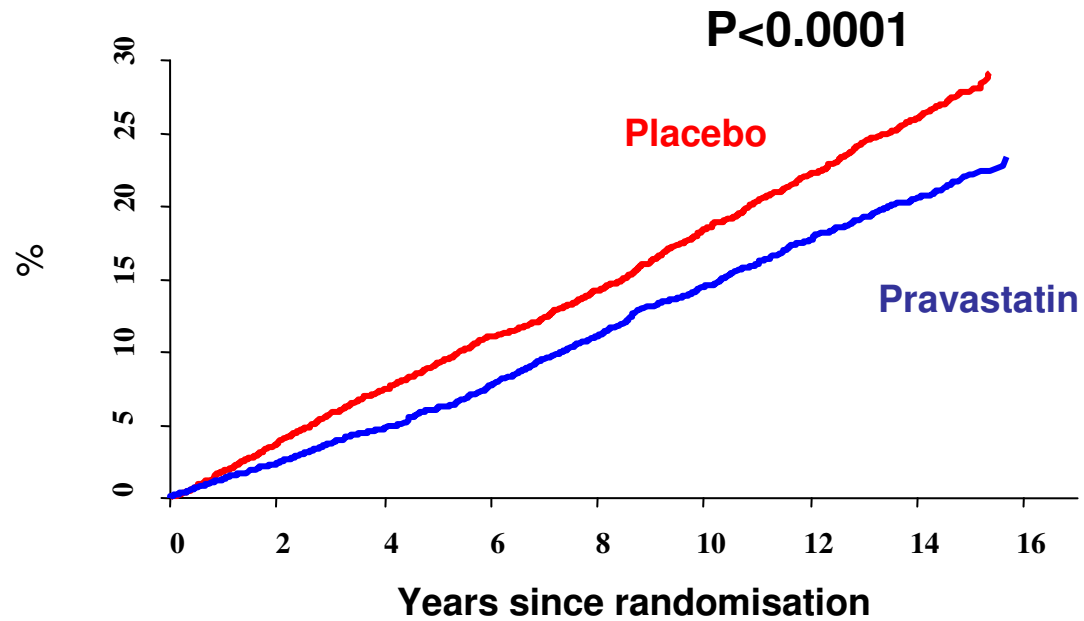
All cause mortality

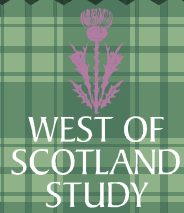




West of Scotland Coronary Prevention Study

CHD death or CHD event





West of Scotland Coronary Prevention Study

Record linkage

- **Quality issues**
 - some coding variation
 - misses non-fatal events out of Scotland
 - high probability of event ascertainment in Scotland, most reliable for broad event classifications
- **Low cost and unbiased**

- **Capture trial data on e-CRF**
- **Supplement with extracts from patient records or disease/event registries**
 - prescriptions, clinical events/ outcomes
- **Monitoring**
 - create individual electronic patient baseline/ event/ treatment summaries
- **Long-term follow-up**
 - extracts from patient records or disease/event registries

