Long-term Follow-up of the MRC/BHF Heart Protection Study (HPS): Information for HPS Participants

Background

HPS was a randomised clinical trial that recruited ~20,500 people between 1994 and 1997. Participants had a high risk of vascular disease and were randomly allocated either 40mg of simvastatin daily or a matching placebo (dummy) pill. They took the pills for around 5-years.

The HPS main trial results were published in 2000, and showed clearly that lowering LDL (or 'bad') cholesterol lowered the risk of heart attacks, strokes and other vascular disease by around one quarter. These results also showed that the longer participants took a statin, the lower their risk of these events. However, at this point, the longer-term (i.e. more than 5-years) risks and benefits of statins were unknown.

To investigate further, after the main trial results were published in 2000, all surviving HPS participants were followed-up for an additional 6-years. This was done via both postal questionnaires and health records from central data registries. This post-trial follow-up found 2 important results:

1. The reductions in fatal and non-fatal heart attacks, strokes and other vascular disease seen in participants who took simvastatin during the original 5-year main trial period continued during the 6-year post-trial period. This was even though many of the participants who had originally been taking the placebo (dummy) pill had started taking a statin during the post-trial follow-up period.
2. During a total 11-year follow-up period, there was no evidence that participants who received simvastatin had any unexpected health risks, with no increase in cancer diagnoses or deaths due to non-vascular causes seen.

Collectively, these results provided strong evidence for starting statins early in high-risk patients, and continuing to take them long-term.

Long-term Follow-up Research

Statins are one of the most commonly prescribed medications worldwide and so there is a lot of interest about their long-term safety. The existing HPS 11-year follow-up has shown no evidence of any harm associated with simvastatin, however some risks may take several decades to emerge.

To investigate this we plan to continue following-up all surviving HPS participants, by using electronic health records from central data registries. From time to time, we will ask NHS Digital (and similar organisations in Wales, Scotland and Northern Ireland) to provide information about medical events such as hospital admissions, cancer diagnoses, dementia diagnoses and deaths that occur in the HPS population. This information will be added to the information previously provided by participants during the main trial at research clinics, and by annual postal questionnaires during post-trial follow-up.

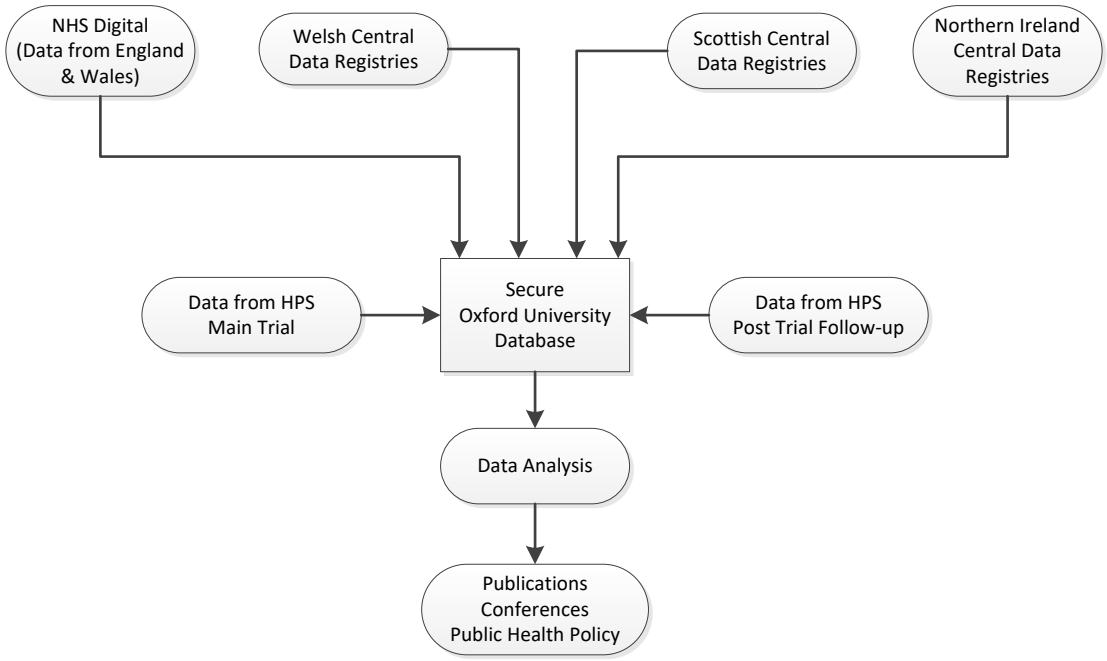
By continuing to follow-up HPS participants for up to 15 more years (to 2035) we hope to provide good evidence that starting a statin earlier has benefits later in life such as a reduced risk of heart attacks, strokes and dementia, while being safe to take long-term. In addition, if statin therapy was shown to reduce dementia risk, this would have a significant impact on population health worldwide.

We will also be using information from blood samples provided by participants during the main trial to investigate genetic risks and causes of vascular and other related diseases (e.g. dementia), and of participant response to simvastatin therapy.

All participant information will be held confidentially and securely by the University of Oxford and used for carefully designed and conducted scientific research only. We will publish the results of our research in reputable, peer reviewed scientific journals and at conferences. Importantly, individual participants will not be identified in any such publication or presentation.

This study is operating under 'Section 251' support provided by the HRA which permits us to use confidential patient information for the purposes that we have described.

Data Flow Diagram



How to opt out of the HPS Long-term Follow-up study

If you were a participant in the HPS main trial and you do not want your data to be included in the HPS Long-term Follow-up study you can opt out.

Please contact us if you would like to discuss your ongoing participation in this study, or if you would like to withdraw (opt out) from it.

Telephone: 0800 585323
Email: hpsinfo@ndph.ox.ac.uk
Address: Dr Richard Bulbulia, Heart Protection Study (HPS), Clinical Trial Service Unit (CTSU), Nuffield Department of Population Health, Richard Doll Building, University of Oxford, Old Road Campus, Roosevelt Drive, Oxford OX3 7LF

You can also contact the study sponsor on 01865 616480 or ctrg@admin.ox.ac.uk.

Where to find out more about HPS

You can find more information about the HPS trial on our website including a publication list and details about how we protect your personal information and your rights as a study participant in the Heart Protection Study Privacy Notice (https://www.ctsu.ox.ac.uk/research/hps).