

# Web-based investigation of statin side-effects

<b>Submission date</b> 01/04/2016	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 12/05/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 14/06/2023	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

## Plain English Summary

Current plain English summary as of 11/10/2017:

### Background and study aims

Statins reduce the risk of heart attacks and strokes, however many patients stop taking statins because they get aches and pains in their muscles. The link between taking statins and aches and pains is not fully understood. Aches and pains are really common among people who don't take statins, and this means when someone taking a statin develops pain, it is really difficult to know whether the pain is caused by their statin. This means it is very difficult for patients and doctors to know whether to stop the statin or to continue. This is an important decision, because by not taking a statin, a patient's risk of a heart attack or stroke goes up by about one third. This study aims to determine whether statins cause muscle pain, thus allowing patients to make well-informed decisions whether to stop them or not.

### Who can participate?

Patients who have recently stopped or wish to stop taking statins due to unwanted muscle symptoms.

### What does the study involve?

Everyone taking part will have agreed to do so voluntarily, knowing the study involves:

- Most people will need a single routine clinical blood test, to confirm if it is safe for the patient to re-start or continue taking statins.
- One main visit to your GP Practice. The Research Nurse will explain everything about the study, including what to do if you have queries. You can ask any questions that you may have.
- If you decide to go ahead, you will have your weight, height and blood pressure recorded and sign a consent form.
- Patients will be given the opportunity to provide a research blood sample for an genetic analysis as part of a larger collaborative effort investigating genetic associations with statins effects. This is entirely optional. Specific results from this blood test will not be given to clinicians or to patients.
- Taking atorvastatin or placebo (dummy treatment) daily for 1 year in 2-months sequences, switching between them in a random order. Neither you, nor your doctor, will know which you are taking in each 2-month period, except in an emergency.
- The study treatment is delivered though the post.
- Completing 7 short questionnaires on your muscle symptoms every 2 months. Patients will be reminded to submit symptom information prior to each data collection period.

- There are a four ways you can choose to complete the questionnaires: 1) via the internet, 2) verbally over the phone, 3) using a mobile phone app or 4) using a conventional paper form.
- Following the 12-months treatment, there will be one phone call or face-to-face appointment with your GP or Research Nurse to discuss your individual results.
- Your results will be based on the information you provided in your questionnaires.
- You can discuss the results with your GP and make a decision about whether you want to continue taking a statin or not.
- Three months after you stopped the study treatment, the study team will contact you to ask if you continued taking statins or not.

What are the possible benefits and risks of participating?

**Benefits** - This study will allow you and your GP to find out if any muscle symptoms you experience happen more when you are taking statins. This may help you to decide with your GP whether to take statins to reduce your risk of cardiovascular disease after the end of the study.  
**Risks** - The study team do not know if statins cause milder muscle symptoms such as pain, which is why we are doing the study. Statins sometimes cause a very rare but serious muscle problem, but in less than 2 in 10,000 people.

Where is the study run from?

The Clinical Trials Unit at the London School of Hygiene and Tropical Medicine (UK)

When is the study starting and how long is it expected to run for?

April 2016 to October 2019

Who is funding the study?

National Institute for Health Research (UK)

Who is the main contact?

1. Professor Liam Smeeth (scientific)
2. Dr Kieran Brack (public)  
statinwise@lshtm.ac.uk

Previous plain English summary:

Background and study aims

Cholesterol is essential for the body to work well, but too much 'bad cholesterol' (called low-density lipoprotein or LDL) is unhealthy. High levels of 'bad cholesterol' in the blood can lead to fatty deposits building up in our arteries. This can increase the risk of developing cardiovascular disease, which includes conditions such as coronary heart disease (leading to angina and heart attack) and stroke. Statins are drugs that are used to reduce the amount of 'bad cholesterol' the body makes while increasing levels of "good" cholesterol (high-density lipoprotein, or HDL). Statins are the most commonly prescribed treatment in the UK. Recently, the number of people eligible to receive statins increased by over 2 million due to updated National Institute for Health and Care Excellence recommendations. Statins are known to cause rare but serious side effects such as rhabdomyolysis (breakdown of muscle tissue) but many patients stop taking statins due to less severe symptoms, such as muscle pain or fatigue. Trials have not found any differences between those taking statins and those taking placebo in terms of these less severe muscle symptoms, but some have questioned whether the information collected was adequate. Given that it is known that statins can reduce heart attacks and strokes, it would be helpful to know how frequently the symptoms experienced during statin use are related to the statin and how frequently related to other causes. This will help inform patients' and doctors' treatment choices. This study is looking at side effects of atorvastatin compared to a matching placebo (dummy pill).

### Who can participate?

Patients who have recently stopped or wish to stop taking statins due to unwanted muscle symptoms.

### What does the study involve?

Each participant is initially randomly allocated to either the atorvastatin group or placebo group. They are all recruited into the study for one year, split into six two-month treatment periods. Each patient is sent their treatment through the post and asked to take it every day for the duration of the study. For the first six months, they receive one treatment. For the second, they receive the other. So, for example, the participants initially in the atorvastatin group will receive the placebo for the second half of the study. This allows them to act as their own control, so at the end of the study, they are able to compare their own level of symptoms between the statin and placebo treatment periods and use this information to help decide the best treatment options. This is called an 'N-of-1' study. Two months is enough for short-term side effects to emerge, and the study's one year duration is brief enough to minimise any adverse impact on cardiovascular outcomes from under-treatment. There is no break between the two treatments (i.e. wash-out period) but symptoms are measured at the end of each treatment period to ensure that they reflect the current treatment. At the end of each two-month period, patients are asked to submit symptom information using a specially-designed mobile app; outcomes are self-reported side effects. If patients are unable to use the mobile app, data can be submitted directly online by the patient or answers to the questions obtained by a researcher through a telephone call. Patients are free to choose a suitable method of follow-up. Patients are reminded to submit symptom information prior to each data collection period. This will be done by email, text, and phone calls. At the end of the trial, patients are shown summaries of their individual results, to help them to decide whether to continue taking statins. Symptom reports are collected 3 months later to assess whether this information impacts subsequent treatment choices and symptom severity. The results are combined from each individual to assess how frequently statins are causing side effects in people who perceive themselves to be intolerant. As part of the study, patients are asked to provide a blood sample for an optional genetic analysis as part of a larger collaborative effort investigating genetic associations with statin effects. Specific results will not be fed back to clinicians or to patients.

### What are the possible benefits and risks of participating?

Not provided at time of registration

### Where is the study run from?

The Keats Group Practice, London (UK)

### When is the study starting and how long is it expected to run for?

April 2016 to April 2019

### Who is funding the study?

National Institute for Health Research (UK)

### Who is the main contact?

1. Professor Liam Smeeth (scientific)
  2. Dr Kieran Brack (public)
- statinwise@lshtm.ac.uk

### Study website

<http://statinwise.lshtm.ac.uk/live/>

## Contact information

### Type(s)

Scientific

### Contact name

Prof Liam Smeeth

### Contact details

London School of Hygiene and Tropical Medicine  
Dept of Non Communicable Diseases  
London  
United Kingdom  
WC1E 7HT

### Type(s)

Public

### Contact name

Dr Kieran Brack

### Contact details

Clinical Trials Unit  
Faculty of Epidemiology & Public Health  
London School of Hygiene & Tropical Medicine  
Keppel Street  
London  
United Kingdom  
WC1E 7HT  
+44 207 958 8195  
statinwise@lshtm.ac.uk

## Additional identifiers

### EudraCT/CTIS number

2016-000141-31

### IRAS number

### ClinicalTrials.gov number

NCT02781064

### Secondary identifying numbers

2016-000141-31

## Study information

### Scientific Title

A series of randomised controlled N-of 1 trials in patients who have discontinued or are considering discontinuing statin use due to muscle-related symptoms to assess if atorvastatin treatment causes more muscle symptoms than placebo.

## **Acronym**

StatinWISE

## **Study hypothesis**

Statins are the most commonly prescribed treatment in the UK. Recently updated NICE guidelines have lowered the threshold for statin use to include all patients with a 10% or greater 10-year risk of cardiovascular disease. Previous randomised trials have established the prevalence of serious adverse effects of statins such as rhabdomyolysis, however, many patients discontinue statins due to less severe symptoms, such as muscle pain or fatigue. Randomised trials have shown no differences between those taking statin and placebo in terms of the prevalence of these side effects (approximately 9%), but currently there is no pathway of care for clinicians to empirically and objectively evaluate whether symptoms reported by a statin-user are caused by the statin itself or the so-called 'nocebo' effect (symptoms reflecting patient expectation of side effects). Given the effectiveness of statins in preventing cardiovascular disease, accurate data on the cause of symptoms experienced during statin use are needed to reliably inform patient and clinician about continuation of use. The proposed StatinWISE trial will provide definitive answers to this important uncertainty about statin therapy.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

1. MRHA Approval, 30/08/2016, ref: Reference – 17072/0009/001-0001
2. South Central – Hampshire A REC Approval ,14/07/2016, ref: Reference – IRA project ID 197990

## **Study design**

A series of randomised, double-blinded N of 1 trials.

## **Primary study design**

Interventional

## **Secondary study design**

Randomised controlled trial

## **Study setting(s)**

GP practice

## **Study type(s)**

Treatment

## **Participant information sheet**

Not available in web format, please use the contact details below to request a patient information sheet. Tel: 0207 299 4684 Email: [statinwise@lshtm.ac.uk](mailto:statinwise@lshtm.ac.uk). Alternatively visit the following web pages: Study PIS (English) - <http://statinwise.lshtm.ac.uk/live/portfolio-view/patient-information-sheet/> Study PIS (Welsh) - <http://statinwise.lshtm.ac.uk/live/portfolio-view/patient-information-sheet-welsh/> Optional Genetics PIS (English) - <http://statinwise.lshtm.ac.uk>

/live/portfolio-view/patient-information-sheet-optional-genetic-study/ Optional Genetics PIS (Welsh) - <http://statinwise.lshtm.ac.uk/live/portfolio-view/patient-informed-consent-form-optional-genetic-study-welsh/>

## Condition

Cardiovascular disease

## Interventions

Current interventions as of 11/10/2017:

Statinwise is a randomised, double blind, placebo controlled N-of-1 trial taking place in a primary care setting. The aim is to quantify the occurrence of self-reported muscle symptoms whilst taking daily atorvastatin and placebo. 200 patients are recruited.

The trial treatment consists of once daily oral administration of Atorvastatin (20mg, capsule form) or a matching placebo (Microcrystalline Cellulose). The treatment phase of the trial will be one year in duration. Atorvastatin or placebo are provided in two-month treatment packs. A blinded placebo, identical in size, colour, smell and packaging to the active statin, has been chosen to prevent knowledge of treatment from affecting symptom scores.

Patients receive their allocated trial medication through the post. There should be no break between treatment periods. However, if for any reason there is a break; patients can restart taking the trial medication as soon as possible. Patients are asked to take the treatment at a time of day convenient to them. Capsules should be swallowed whole. Patients are given written instructions on how to take the study medication in English or Welsh.

At the start of each treatment period, patients are asked to inform the trial team about the first date of study medication. A Freephone telephone number and a pre-paid postage reply slip is available for the patient to use, whichever is easier to ensure data collection occur on the correct days. At the end of each treatment period patients are asked to report their pain scores using questionnaires. There are a four ways to choose to complete these: 1) via the internet, 2) verbally over the phone, 3) using a mobile phone app or 4) using a conventional paper form.

During the last week of the last treatment period, the Research Nurse contacts patients to thank them for their participation and to inform them that this is the last treatment period. Patients will be informed that they receive their individual results at the beginning of month 14. The Research Nurse and patient should arrange a telephone or face-to-face appointment to discuss the individual results during month 14. The Research Nurse also informs patients that if they want to continue taking statin without a break, to arrange a separate clinical appointment with their GP prior to the end of the treatment period.

At month 15, trial staff contact the patient to document their decision to continue statin use and whether their results helped them reach this decision. This will be the last data collection point of the trial for each patient.

Throughout the trial, continued patient care will be at the discretion of their GP. In primary care, the patient will be recorded as having an ongoing statin prescription.

1. Where treatment with an interacting drug is needed that will be for less than one-month duration, the patient will be asked to stop the trial treatment for that period.
2. Where treatment with an interacting drug is needed for longer than one month, the patient will be asked to withdraw from study treatment completely.

#### Previous interventions:

Statinwise is a randomised, double blind, placebo controlled N-of-1 trial taking place in a primary care setting, to quantify the occurrence of self-reported muscle symptoms whilst taking daily atorvastatin. A total of 200 patients who fulfil the eligibility criteria will be recruited. The trial treatment consists of once daily oral administration of Atorvastatin (20mg) capsules, which will be compared with matching placebo (Microcrystalline Cellulose). The treatment phase of the trial will be one year in duration for each patient. A blinded placebo, identical in size, colour, smell and packaging to the active statin, has been chosen to prevent knowledge of treatment from affecting symptom scores.

Patients will receive their allocated trial medications through the post and they will be asked to take the study medication daily through the six two-month treatment periods. Ideally there should be no break between treatment periods. However, if for any reason there is a break; patients can simply restart taking the trial medication as soon as possible.

Patients will be asked to take one capsule orally once daily at a time of day convenient to them. Capsules should be swallowed whole. Patients will be given written instructions on how to take the study medication. At the start of each two month treatment period, patients will be asked to inform the trial team about their first date of study medication use using the trial's mobile application (app), email, text message, Freephone telephone service or a pre-paid postage reply slip, whichever is easier to ensure data collection occur on the correct days. A Freephone telephone number will be provided for patients to call if they have any questions. Adherence to the study medication will be collected on the same days as other data as part of the outcome data collection.

During the last week of treatment period, the Research Nurse will contact patients to thank them for their participation so far, inform them that this is the last treatment period, and that they, together with their GP, will receive their individual results at the beginning of month 14. The Research Nurse and patient will arrange a telephone or face to face appointment to discuss the individual results during month 14. The Research Nurse will also inform patients that if they want to continue taking statin without a break, to arrange a separate clinical appointment with their GP prior to the end of the treatment period.

At month 15, trial staff will email/telephone the patient to document their decision on future statin use and whether their results helped reach this decision. This will be the last data collection point of the trial.

Throughout the trial, continued patient care will be at the discretion of their GP. In primary care, the patient will be recorded as having an ongoing statin prescription.

1. Where treatment with an interacting drug is needed that will be for less than one-month duration, the patient will be asked to stop the trial treatment for that period.
2. Where treatment with an interacting drug is needed for longer than one month, the patient will be asked to withdraw from study treatment completely.

This will be the last data collection point for the study.

#### **Intervention Type**

Drug

#### **Phase**

Phase IV

**Drug/device/biological/vaccine name(s)**

Atorvastatin

**Primary outcome measure**

Muscle symptoms (pain, weakness, tenderness, stiffness or cramp) reported every 7-week during treatment, measured using the Visual Analogue Score (VAS) score

**Secondary outcome measures**

Relationship between individual trial result and patient decision whether to continue statins long term at month 15, measured by checking if a statin prescription was issued by the General Practitioner.

**Overall study start date**

01/04/2016

**Overall study end date**

30/09/2019

**Eligibility****Participant inclusion criteria**

1. Adults (aged 16 and over)
2. Prescribed statin treatment in the last 3 years
3. Stopped OR considering stopping statin treatment due to muscle symptoms
4. Provided fully informed consent

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

16 Years

**Sex**

Both

**Target number of participants**

200

**Total final enrolment**

200

**Participant exclusion criteria**

1. Any previously documented serum alanine aminotransferase (ALT) levels at or above three times the upper limit of normal
2. Have persistent, generalised, unexplained muscle pain (whether associated or not with statin use) and have creatinine kinase (CK) levels greater than 5 times the upper limit of normal
3. Should not be using atorvastatin 20mg daily in the opinion of the general practitioner



**Recruitment start date**

01/12/2016

**Recruitment end date**

04/06/2018

## Locations

**Countries of recruitment**

England

United Kingdom

Wales

**Study participating centre****Albion Street Practice**

87 Albion Street

Rotherhithe

London

United Kingdom

SE16 7JX

**Study participating centre****Bay Medical**

Heysham Primary Care Centre

Middleton Way

Heysham

United Kingdom

-

**Study participating centre****Bentley Surgery**

128 High Street

Bentley

Doncaster

United Kingdom

DN5 0AT

**Study participating centre****Brigstock & South Norwood Partnership**

141 Brigstock Road

Thornton Heath  
Surrey  
United Kingdom  
CR7 7JN

**Study participating centre**  
**Bromley Common Practice**  
Crown Medical Centre  
3 Mackintosh Street  
Bromley  
United Kingdom  
BR2 9GT

**Study participating centre**  
**Brownlow Health**  
70 Pembroke Place  
Liverpool  
United Kingdom  
L69 3GF

**Study participating centre**  
**Clarence Medical Centre**  
West Kinmel Street  
Wales  
Rhyl  
United Kingdom  
LL18 1DA

**Study participating centre**  
**Cleverleys Group Practice**  
Kelso Avenue, Lancashire  
Thornton-Cleveleys  
United Kingdom  
FY5 3LF

**Study participating centre**  
**Conisbrough Group Practice**  
Stone Castle Centre  
Doncaster

Conisbrough  
United Kingdom  
DN12 3JW

**Study participating centre**  
**Creffield Medical Centre**  
15 Cavalry Road  
Colchester  
United Kingdom  
CO2 7GH

**Study participating centre**  
**Everglades Medical Practice**  
Grahame Park Health Centre  
The Concourse  
London  
United Kingdom  
NW9 5XT

**Study participating centre**  
**The Exchange Surgery**  
2-8 Gracefields Gardens  
London  
United Kingdom  
SW16 2ST

**Study participating centre**  
**Falkland Surgery**  
Falkland Way  
Bradwell  
Great Yarmouth  
United Kingdom  
NR31 8RW

**Study participating centre**  
**Freshney (Littlefields) Green Primary Care Centre**  
Sorrel Road  
Grimsby  
United Kingdom  
DN34 4GB

**Study participating centre**  
**Great Sutton Medical Centre**  
Old Chester Road  
Ellesmere Port  
Chester  
United Kingdom  
CH66 3SP

**Study participating centre**  
**Hampstead Group Practice**  
75 Fleet Road  
London  
United Kingdom  
NW3 2QU

**Study participating centre**  
**Hope Family Medical Centre**  
Hope Health Centre  
Hawarden Road  
Hope  
Nr Wrexham  
United Kingdom  
LL12 9NP

**Study participating centre**  
**Hornsey Rise Health Centre**  
Hornsey Rise Health Centre, Hornsey Rise  
London  
United Kingdom  
N19 3YU

**Study participating centre**  
**Hoveton and Wroxham Medical Centre**  
Stalham Road  
Norfolk  
Hoveton  
United Kingdom  
NR12 8DU

**Study participating centre**

**Hurley Clinic**

Kennington Lane  
Lambeth  
London  
United Kingdom  
SE11 4HJ

**Study participating centre**

**Jorvik Gillygate Practice**

Woolpack Surgery  
Stonebow  
York  
United Kingdom  
-

**Study participating centre**

**Keats Medical Practice**

Keats Medical Practice, 1b Downshire Hill  
United Kingdom  
NW3 1LR

**Study participating centre**

**Kings Road Surgery, Mumbles**

2-6 Kings Road, Mumbles  
Swansea  
United Kingdom  
SA3 4AJ

**Study participating centre**

**Long Stratton Medical Partnership**

Swan Lane, Tharston, Norfolk  
Norwich  
United Kingdom  
NR15 2UY

**Study participating centre**

**Mathukia's Surgery**

281 Ilford Lane, Essex

Ilford  
United Kingdom  
IG1 2SF

**Study participating centre**  
**Mattishall & Lenwade Surgeries**  
15 Dereham Road, Mattishall, Norfolk  
Dereham  
United Kingdom  
NR20 4QA

**Study participating centre**  
**Mayfield Surgery**  
246 Roehampton Lane  
London  
United Kingdom  
SW15 4AA

**Study participating centre**  
**Mitcham Family Practice**  
55 Mortimer Road  
Surrey  
Mitcham  
United Kingdom  
CR4 3HS

**Study participating centre**  
**North House Surgery**  
28 North Street  
Ripon  
United Kingdom  
HG4 1HL

**Study participating centre**  
**Oak Lodge Medical Centre**  
234 Burnt Oak Lane  
Edgware  
London  
United Kingdom  
HA8 0AP

**Study participating centre**

**Oak Tree Surgery**

Whitethorn Drive, Brackla, Bridgend  
United Kingdom  
CF 31 2PQ

**Study participating centre**

**Open Door Surgery**

47 Boundaries Road  
Balham  
London  
United Kingdom  
SW12 8EU

**Study participating centre**

**Parliament Hill Medical Centre**

113-117 Highgate Road  
London  
United Kingdom  
NW5 1TR

**Study participating centre**

**Paxton Green Group Practice**

1 Alleyn Park  
London  
United Kingdom  
SE21 8AU

**Study participating centre**

**Pendle View Medical Centre**

47 Arthur Street, Brierfield, Nelson, Lancashire  
United Kingdom  
BB9 5RZ

**Study participating centre**

**Queen Square Medical Practice**

2 Queen Square

Lancaster  
United Kingdom  
LA1 1RP

**Study participating centre**

**Regent House Surgery**

21 Regent Road  
Chorley  
United Kingdom  
PR7 2DH

**Study participating centre**

**Riverside Medical Practice**

Hobart House, Vauxhall  
London  
United Kingdom  
SW8 2JB

**Study participating centre**

**Rosedale Surgery**

Ashburnham Way, Carlton Colville, Lowestoft, Suffolk  
United Kingdom  
NR33 8LG

**Study participating centre**

**School Lane Surgery**

School Lane  
Thetford  
United Kingdom  
IP24 2AG

**Study participating centre**

**Scott Practice**

Greenfield Lane, Balby, Doncaster  
United Kingdom  
DN4 0TG

**Study participating centre**



**Snaith & Rawcliffe Medical Group The Marshes Surgery**  
But Lane Snaith Goole, East Yorkshire  
United Kingdom  
DN14 9DY

**Study participating centre**  
**Station House Surgery**  
Station Rd, Kendal, Cumbria  
United Kingdom  
LA9 6SA

**Study participating centre**  
**Strawberry Place Surgery**  
5 Strawberry Place, Morrision  
Swansea  
United Kingdom  
SA6 7AQ

**Study participating centre**  
**Streatham Common Practice**  
St Andrews Church Room, Guildersfield Road  
London  
United Kingdom  
SW16 5LS

**Study participating centre**  
**Tottenham Health Centre**  
759 High Road, Tottenham  
London  
United Kingdom  
N17 8AH

**Study participating centre**  
**Vanbrugh Group Practice**  
Greenwich Square Health Centre, 2nd Floor, 12 Lombarde Square  
London  
United Kingdom  
SE10 9GB

**Study participating centre**

**Village Practice Thornton**

Thornton Medical Centre, Church Road  
Thornton-Cleveleys  
United Kingdom  
FY5 2TZ

**Study participating centre**

**Watling Medical Centre**

108 Watling Avenue, Burnt Oak, Edgware  
United Kingdom  
HA8 0NR

**Study participating centre**

**West Hampstead Medical Centre**

9 Solent Road  
London  
United Kingdom  
NW6 1TP

**Study participating centre**

**Windermere & Bowness Surgery**

Goodly Dale, Windermere, Cumbria  
United Kingdom  
LA23 2EG

**Study participating centre**

**Woodlands Practice**

11 Red Hill, Chislehurst, Kent  
United Kingdom  
BR7 6DB

**Study participating centre**

**William Harvey Heart Centre**

Barts and The London School of Medicine & Dentistry  
William Harvey Heart Centre  
Charterhouse Square  
United Kingdom  
EC1M 6BQ

**Study participating centre**  
**Wallington Family Practice**  
Jubilee Health Centre  
Shotfield  
Wallington  
United Kingdom  
SM6 0HY

**Study participating centre**  
**Vale of Neath**  
102 High Street, Glynneath, Neath  
Wales  
United Kingdom  
SA11 5AL

**Study participating centre**  
**Honor Oak Group Practice**  
20 Turnham Road,  
London  
United Kingdom  
SE4 2LA

**Study participating centre**  
**Bicester Health Centre**  
The Health Centre, Coker Close, Bicester, Oxon  
United Kingdom  
OX26 6AT

**Study participating centre**  
**Beechtree Surgery**  
68 Doncaster Road  
Selby  
United Kingdom  
YO8 9AJ

## **Sponsor information**

**Organisation**  
London School of Hygiene and Tropical Medicine

**Sponsor details**

Keppel Street  
London  
England  
United Kingdom  
WC1E 7HT

**Sponsor type**

University/education

**Website**

<https://www.lshtm.ac.uk>

**ROR**

<https://ror.org/00a0jsq62>

**Funder(s)****Funder type**

Government

**Funder Name**

National Institute for Health Research

**Alternative Name(s)**

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom

**Results and Publications****Publication and dissemination plan**

Current publication and dissemination plan as of 11/10/2017:

The trial protocol and results will be published in peer-reviewed journals. All publications will follow CONSORT guidelines. Links to the publication will be provided in all applicable trial registers. Dissemination of results to patients will take place via the media, trial website and

relevant patient organisations. Collaborating investigators will play a vital role in disseminating the results to colleagues and patients.

The success of the trial depends entirely upon the collaboration of nurses and doctors in the participating practices and those who hold key responsibility for the trial. Hence, credit for the study will be assigned to the key collaborator(s) from a participating site as it is crucial that those taking credit for the work have actually carried it out. The results of the trial will be reported first to trial collaborators.

### **Intention to publish date**

31/03/2020

### **Individual participant data (IPD) sharing plan**

For participant level data, please see the study website (<http://statinwise.lshtm.ac.uk/live/>)

Previous publication and dissemination plan:

The trial protocol and results will be published in peer-reviewed journals. All publications will follow the CONSORT statement.<sup>21</sup> Links to the publication will be provided in all applicable trial registers. Dissemination of results to patients will take place via the media, trial website and relevant patient organisations. Collaborating investigators will play a vital role in disseminating the results to colleagues and patients.

The success of the trial depends entirely upon the collaboration of nurses and doctors in the participating practices and those who hold key responsibility for the trial. Hence, credit for the study will be assigned to the key collaborator(s) from a participating site as it is crucial that those taking credit for the work have actually carried it out. The results of the trial will be reported first to trial collaborators.

IPD sharing statement:

For participant level data, please see the study website (<http://statinwise.lshtm.ac.uk/live/>)

### **IPD sharing plan summary**

Stored in repository

#### **Study outputs**

<b>Output type</b>	<b>Details</b>	<b>Date created</b>	<b>Date added</b>	<b>Peer reviewed?</b>	<b>Patient-facing?</b>
<a href="#">Protocol article</a>	protocol	01/12/2017		Yes	No
<a href="#">Results article</a>	results	24/02/2021	25/02/2021	Yes	No
<a href="#">Results article</a>	results	01/03/2021	15/03/2021	Yes	No
<a href="#">Results article</a>		05/11/2019	14/06/2023	Yes	No