

# TRial of Atorvastatin for the primary prevention of Cardiovascular Events in Rheumatoid Arthritis

<b>Submission date</b> 14/06/2006	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
<b>Registration date</b> 26/07/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 06/02/2020	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

### Study information

**Scientific Title**  
TRial of Atorvastatin for the primary prevention of Cardiovascular Events in Rheumatoid Arthritis

**Acronym**  
TRACE/RA

## **Study objectives**

The principal research question is to establish whether atorvastatin, used in conjunction with standard therapy for rheumatoid arthritis will protect rheumatoid arthritis sufferers aged 40 years and above from fatal and non-fatal atherosclerotic events.

Please note that as of 30/04/2008 this trial was updated. All changes can be found in the relevant field under the above date. Please also note that the overall trial start and end dates have been updated. The previous dates of this trial were:

Previous overall trial start date: 01/12/2006

Previous overall trial end date: 01/12/2014

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Southampton and South West Hampshire Research Ethics Committee B, 20/12/2006, ref: 06/Q1704/171

## **Study design**

Multicentre randomised double-blind placebo-controlled trial

## **Primary study design**

Intentional

## **Study type(s)**

Treatment

## **Health condition(s) or problem(s) studied**

Rheumatoid arthritis

## **Interventions**

Patients will be randomised to either the atorvastatin arm (40 mg of atorvastatin oral tablet taken once daily) or placebo arm (placebo atorvastatin oral tablet taken once daily) of the trial.

## **Intervention Type**

Drug

## **Phase**

Not Applicable

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

Atorvastatin

## **Primary outcome(s)**

Cardiovascular primary endpoint for all patients: all cardiovascular events (analysed by time to FIRST event) briefly defined as: fatal myocardial infarction, other acute coronary heart disease death, definite or probable hospital-verified non-fatal acute myocardial infarction, resuscitated cardiac arrest, definite silent myocardial infarction verified by an electrocardiogram (ECG), coronary revascularisation procedures, hospital admission for acute coronary syndrome, fatal

stroke or peripheral arterial event (using predefined standard definitions) and hospital-verified non-fatal stroke or peripheral atherosclerotic events. The endpoints assessment committee will adjudicate this.

Rheumatology primary outcome (disease activity substudy only): Disease Activity Score 28 (DAS28) at six months, response will be judged using the European League Against Rheumatism (EULAR) response criteria.

### **Key secondary outcome(s)**

Secondary endpoints for all patients:

1. All-cause mortality
2. Changes in fasting lipids and C-Reactive Protein (CRP)
3. Functional outcome (assessed by the Health Assessment Questionnaire [HAQ] and EuroQoL instrument [EQ5D])
4. Statin safety-related outcomes.

Rheumatology secondary outcomes (disease activity substudy only): Disease-Modifying Anti-Rheumatic Drug (DMARD) changes, DAS28 at years one, two and five.

Not applicable as of 30/04/2008:

Radiological outcome (assessed by the Larsen score in X-rays of hands and wrists - only at year two.

### **Completion date**

01/08/2014

## **Eligibility**

### **Key inclusion criteria**

Current inclusion criteria as of 30/04/2008:

1. Patients must satisfy the 1987 ACR criteria for rheumatoid arthritis applied cumulatively
2. Patients must be aged more than 50 or have had RA disease duration for more than 10 years
3. Patients must provide their written informed consent

Previous inclusion criteria:

1. Patients must satisfy the 1987 ACR criteria for rheumatoid arthritis applied cumulatively
2. Patients must be 40 years or older
3. Patients must provide their written informed consent

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Sex**

All

## **Total final enrolment**

3002

### **Key exclusion criteria**

Current exclusion criteria as of 30/04/2008:

1. Patients who are pregnant or women of child-bearing age not using adequate contraception
2. Known primary muscle disorder
3. Known atherosclerotic disease
4. Known familial hyperlipidamia requiring drug therapy
5. Known diabetes
6. Known hypersensitivity or intolerance to statins
7. Active liver disease or hepatic dysfunction with Aspartate aminotransferase (AST) or Alanine aminotransferase (ALT) more than two times Upper Limit of Normal (ULN)
8. Severe renal dysfunction (creatinine >150 micromol/l)
9. Creatinine phosphokinase (CK) more than three times ULN
10. Uncontrolled hypothyroidism (defined as any elevation of Thyroid-Stimulating Hormone [TSH] above ULN)
11. Participation in another clinical trial concurrently or within 30 days prior to screening for entry into this study (patients may be participating in an observational study such as the British Society for Rheumatology Biologics register)
12. Other serious illness or significant abnormalities that may compromise the patient's safety or successful participation in the study
13. Any illness which, in the doctor's opinion, means that the patient is unable to give informed consent
14. Known alcohol abuse

Previous exclusion criteria:

1. Patients who are pregnant or women of child-bearing age not using adequate contraception
2. Known primary muscle disorder
3. Known atherosclerotic disease
4. Known familial hyperlipidamia requiring drug therapy
5. Known diabetes
6. Calculated absolute ten year Cardio-Vascular Disease (CVD) risk of 20% or higher, using the Joint British Societies revised risk calculator
7. Known hypersensitivity or intolerance to statins
8. Active liver disease or hepatic dysfunction with Aspartate aminotransferase (AST) or Alanine aminotransferase (ALT) more than two times Upper Limit of Normal (ULN)
9. Severe renal dysfunction (creatinine >150 micromol/l)
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14. Any illness which, in the doctor's opinion, means that the patient is unable to give informed consent
15. Known alcohol abuse

### **Date of first enrolment**

07/08/2007

**Date of final enrolment**

01/08/2014

## Locations

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Dudley Group of Hospitals NHS Trust**

Dudley

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DY1 2HQ

## Sponsor information

**Organisation**

University of Manchester (UK)

**ROR**

<https://ror.org/027m9bs27>

## Funder(s)

**Funder type**

Research organisation

**Funder Name**

British Heart Foundation (UK)

**Alternative Name(s)**

The British Heart Foundation, the\_bhf, BHF

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Trusts, charities, foundations (both public and private)

**Location**

United Kingdom

**Funder Name**

Arthritis Research Campaign (ARC) (UK) (ref: 16514)

**Funder Name**

Pfizer UK Ltd (UK)

## Results and Publications

### Individual participant data (IPD) sharing plan

**IPD sharing plan summary**

Not provided at time of registration

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	20/04/2015		Yes	No
<a href="#">Results article</a>	results	01/09/2019	06/02/2020	Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes