ISRCTN43070564 https://doi.org/10.1186/ISRCTN43070564

# Registry to provide contemporary information regarding characteristics, management and outcomes of outpatients with stable coronary artery disease

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|---|---|---|
| **Submission date**<br>13/05/2011 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol |
| **Registration date**<br>13/06/2011 | **Overall study status**<br>Completed | [_] Statistical analysis plan<br>[X] Results |
| **Last Edited**<br>09/01/2023 | **Condition category**<br>Circulatory System | [_] Individual participant data |

**Plain English summary of protocol**
Not provided at time of registration and not expected to be available in the future

**Study website**
http://www.clarify-registry.com

## Contact information

**Type(s)**
Scientific

**Contact name**
Prof Philippe Gabriel Steg

**Contact details**
Centre Hospitalier Bichat-Claude Bernard
46 Rue Henri Huchard
Paris
France
75018

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

### Secondary identifying numbers
N/A

# Study information

### Scientific Title
ProspeCtive observational LongitudinAl RegIstry oF patients with stable coronary arterY disease

### Acronym
CLARIFY

### Study objectives
Most of the data pertaining to patients with stable coronary artery disease come from randomised clinical trials involving highly selective patient population. This large international observational registry will attempt to provide contemporary information regarding characteristics, management and outcomes of outpatients with stable coronary artery disease.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
National Research Ethics Service, Isle of Wight, Portsmouth and Southeast Hampshire Research Ethics Committee, UK approved on 20/11/2009. All other centres obtained ethics approval before recruitment of the first participant.

### Study design
Multicentre prospective observational longitudinal study

### Primary study design
Observational

### Secondary study design
Longitudinal study

### Study setting(s)
Hospital

### Study type(s)
Screening

### Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

### Health condition(s) or problem(s) studied
Coronary artery disease

### Interventions

The registry attempted to collect representative data for each of the participating countries. Representativeness is ensured by a two-tiered process:
1. Determination of physician type in charge of outpatients with stable CAD in a given country and targeting of an appropriate proportion of each of this physician's specialties
2. For each physician, enrollment of consecutive, eligible patients. The data will be collected prospectively using an electronic standardised international case report form (translated into the local language) at baseline and annually during 5 years follow up (at 12+/-3, 24+/-3, 36+/-3, 48+/-3, and 60+/-3 months).

### Intervention Type
Other

### Phase
Not Applicable

### Primary outcome measure
Information collected at baseline will include demographics, medical history, risk factors, employment status, physical examination, heart rate, laboratory values (if available), and current chronic medical treatments. Each annual follow-up visit will collect information regarding clinical events, hospitalisations, interventions, death, employment status, physical examination, heart rate, laboratory values (if available) and current medical therapy (cardiovascular and non-cardiovascular).

### Secondary outcome measures
No secondary outcome measures

### Overall study start date
01/11/2009

### Completion date
30/07/2015

## Eligibility

### Key inclusion criteria
Outpatients with stable coronary artery disease, proven by history of at least one of the following criteria:
1. Documented myocardial infarction (more than 3 months ago)
2. Coronary stenosis of more than 50% proven by coronary angiography
3. Chest pain with proven myocardial ischemia
4. Coronary artery bypass grafting surgery or percutaneous coronary intervention (more than 3 months ago)

### Participant type(s)
Patient

### Age group
Adult

### Sex
Both

### Target number of participants
33,000

### Total final enrolment
32954

### Key exclusion criteria
1. Patients hospitalised for cardiovascular disease within last 3 months
2. Patients with planned revascularisation
3. Conditions hampering the participation or the 5-year follow-up

### Date of first enrolment
01/11/2009

### Date of final enrolment
30/07/2015

## Locations

### Countries of recruitment
Argentina

Australia

Austria

Bahrain

Barbados

Belgium

Brazil

Bulgaria

Canada

China

Czech Republic

Denmark

France

Germany

Greece

Hungary

Ireland

Italy

Korea, South

Kuwait

Latvia

Lithuania

Malaysia

Mexico

Netherlands

Oman

Poland

Portugal

Qatar

Romania

Russian Federation

Saudi Arabia

Singapore

Slovakia

Slovenia

South Africa

Spain

Switzerland

Thailand

Ukraine

United Arab Emirates

United Kingdom

Viet Nam

**Study participating centre**
**Centre Hospitalier Bichat-Claude Bernard**
Paris
France
75018

# Sponsor information

**Organisation**
Institut de Recherches Internationales Servier (France)

**Sponsor details**
50 rue Carnot
Suresnes
France
92284

**Sponsor type**
Industry

**Website**
http://www.servier.com/

**ROR**
https://ror.org/034e7c066

# Funder(s)

**Funder type**
Industry

**Funder Name**
Institut de Recherches Internationales Servier (France)

# Results and Publications

## Publication and dissemination plan
Not provided at time of registration

## Intention to publish date

## Individual participant data (IPD) sharing plan
Not provided at time of registration

## IPD sharing plan summary
Not provided at time of registration

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 22/07/2014 | | Yes | No |
| Results article | results | 01/10/2014 | | Yes | No |
| Results article | results | 27/04/2015 | | Yes | No |
| Results article | results | 01/08/2015 | | Yes | No |
| Results article | results | 01/01/2016 | | Yes | No |
| Results article | results | 01/07/2019 | 03/06/2020 | Yes | No |
| Results article | 5-year results | 15/07/2021 | 16/07/2021 | Yes | No |
| Results article | | 07/01/2023 | 09/01/2023 | Yes | No |