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

Submission date 13/05/2011	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 13/06/2011	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 09/01/2023	**Condition category** 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

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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