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Tor Vergata Atherosclerosis Registry: Identification of biomarkers for cardiovascular events and mortality

Submission date 28/06/2016	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 19/10/2016	**Overall study status** Ongoing	[_] Statistical analysis plan [_] Results
Last Edited 26/10/2016	**Condition category** Circulatory System	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims:
Atherosclerosis is a serious disease where a fatty substance, called plaque, buildsup in the arteries. Over time, plaque causes hardening and narrowing of the arteries, which leads to reduced flow of blood through the blood vessels. It is a major cause of cardiovascular disease (disease of the heart and/or blood vessels) which can lead to potentially fatal complications such as heart attack or stroke (major cardiovascular events). Over the last 20 years, the death toll from cardiovascular disease (CVD) has decreased, however for those with type 2 diabetes (a condition in which people are unable to control their blood sugar) have a higher risk of dying from CVD than non-diabetic patients. In addition, patients with type 2 diabetes have a higher risk of developing complications if they undergo surgery on the heart or blood vessels. Currently, little is known about the effect of undiagnosed type 2 diabetes on the risk of dying from complications relating to CVD, and the only data available only looks at the effects in the short-term. The Tor Vergata Atherosclerosis Study has been designed to follow patients with previous CVD and evaluate the risk of new CVD events through the creation of a registry. The aim of this registry is to investigate the extent to which undiagnosed diabetes and atherosclerosis severity affect the occurrence of a second major cardiovascular event in high risk individuals. The aim of this study is to follow patients for 20 years in order to find out whether problems controlling blood sugar are related to death from CVD.

Who can participate?
Male and female patients aged between 40-85 years with atherosclerosis.

What does the study involve?
At the start of the study, participants undergo a metabolic assessment. Participants then receive yearly follow up calls for the next 20 years to assess how many die, how many die from CVD and how many have a non-fatal cardiovascular event (such as a heart attack or stroke).

What are the possible benefits and risks of participating?
A potential benefit of taking part in the study is that any problems with the way the body processes glucose (sugar) will be identified. There are no significant risks of participating.

Where is the study run from?
Center for Atherosclerosis, University Hospital of Rome Tor Vergata (Italy)

When is study starting and how long is it expected to run for?
January 2007 to December 2027

Who is the main contact?
Professor Massimo Federici
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
TVAR 1

Study information

Scientific Title
Tor Vergata Atherosclerosis Registry: a cohort study to understand the links between glucose and metabolic disorders and cardiovascular mortality

Acronym
TVAR

Study objectives
Undiagnosed glucose metabolism increases cardiovascular mortality.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethic Committee University Hospital Tor Vergata - Rome, 29/04/2008

Study design
Observational longitudinal study

Primary study design
Observational

Secondary study design
Longitudinal study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Atherosclerosis and diabetes

Interventions
Patients enrolled in the study will undergo a metabolic assessment at baseline to evaluate the degree of glucose impairment.

The basal metabolic assessment include:
1. Fasting plasma glucose, fasting plasma insulin, glycated Hemoglobin (HbA1c) and C-peptide levels, total cholesterol, HDL cholesterol, LDL cholesterol, triglycerides and indexes of insulin resistance, such as HOMA IR, QUICKI, Matsuda index, and HOMA beta index for insulin secretion in diabetic patients.
2. Fasting plasma glucose, fasting plasma insulin, glycated Hemoglobin (HbA1c) and C-peptide levels, total cholesterol, HDL cholesterol, LDL cholesterol, triglycerides and indexes of insulin resistance, such as HOMA IR, QUICKI, Matsuda index, and HOMA beta index for insulin and oral glucose tolerance test (OGTT) in non diabetic patients.

In patients that undergo Carotid Artery Endoarterectomy, atherosclerotic plaques are collected. The atheroma is then divided in two parts: one part was preserved in formalin for histology analysis and the other part was immersed in liquid nitrogen for further analysis.

The follow-up will be performed annually by phone in order to investigate the occurrence of new fatal or non-fatal cardiovascular events. The total duration of observation will be for 20 years.

Intervention Type
Other

Primary outcome measure
1. Mortality is measured using the phone interview confirmed by hospital records at yearly follow-up
2. Cardiovascular mortality is measured using the phone interview confirmed by hospital records at yearly follow-up

Secondary outcome measures
Non-fatal cardiovascular events (AMI and Stroke) are measured using the phone interview confirmed by hospital records at yearly follow-up.

Overall study start date
01/01/2007

Completion date
31/12/2025

Eligibility

Key inclusion criteria
Patients were diagnosed with established and documented atherosclerotic vascular disease at the atherosclerosis ambulatory clinic that includes cardiology, diabetology and vascular surgery specialists. All the patients have had a major CV event or undergone a vascular procedure for significant vascular stenosis.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
1000

Key exclusion criteria
1. Liver disease
2. Renal insufficiency
3. Heart failure
4. Coagulopathy
5. Any other severe systemic disease
6. Positive blood tests for HIV, hepatitis B, or hepatitis C

Date of first enrolment
01/01/2007

Date of final enrolment
31/12/2015

Locations

Countries of recruitment
Italy

Study participating centre
University Hospital of Rome Tor Vergata
Center for Atherosclerosis
Via Montpellier
Rome
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Sponsor information

Organisation
University of Rome Tor Vergata Department of Systems Medicine

Sponsor details
Via Montpellier 1
Rome
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00133

Sponsor type
University/education

ROR
https://ror.org/02p77k626

Funder(s)

Funder type
University/education

Funder Name
University of Rome Tor Vergata (Università degli Studi di Roma Tor Vergata)

Alternative Name(s)
University of Rome Tor Vergata

Funding Body Type

Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Italy

Results and Publications

Publication and dissemination plan
Planned publication in a peer reviewed journal.

Intention to publish date
31/12/2027

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date