

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 Completed	☐ 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, builds up 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

federicm@uniroma2.it

Contact information

Type(s)

Scientific

Contact name

Prof Massimo Federici

Contact details

University of Rome Tor Vergata
Department of Systems Medicine
Via Montpellier 1
Rome
Italy
00133

Additional identifiers

Protocol serial number

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

Study type(s)

Other

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

Italy

00133

Sponsor information

Organisation

University of Rome Tor Vergata Department of Systems Medicine

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Data sharing statement to be made available at a later date