

# General Practitioners and Nephrologists for Outpatient Assistance

<b>Submission date</b> 16/01/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 18/02/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 18/02/2010	<b>Condition category</b> Urological and Genital Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

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

## Contact information

**Type(s)**  
Scientific

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Italy  
16100

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
N/A

## Study information

**Scientific Title**

## Chronic kidney disease and cardiovascular risk in primary care

### Acronym

GENOA

### Study objectives

To analyse the influence of estimated glomerular filtration rate and proteinuria on survival, free of cardiovascular and renal events, and to test the accuracy of calculators including renal function indices in predicting cardiovascular outcomes of primary care patients

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Trial not requiring ethical approval as study design is completely adherent to the recommendations issued by the local ethical committee of Azienda Ospedaliera S. Martino (Genova, Italy) and in accordance to the guidelines issued by the Helsinki declaration.

### Study design

Retrospective analysis and observational prospective study

### Primary study design

Observational

### Secondary study design

Other

### Study setting(s)

GP practice

### Study type(s)

Other

### Participant information sheet

Not available in web format, please contact [noberasco@ebinobisas.191.it](mailto:noberasco@ebinobisas.191.it) to request a patient information sheet.

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

Chronic kidney disease

### Interventions

Data will be extracted from the Health Search Database (HSD). The HSD was set up in 1998 and managed by the Italian College of GPs. The HSD contains information provided by more than 650 Italian GPs, and includes data on more than 1,000,000 individuals.

Demographic, clinical and laboratory data, namely age, sex, body weight, height, blood pressure (BP) values, serum lipids, and serum creatinine will be evaluated for each patient. The presence of diabetes, smoking habits, and the occurrence of previous major cardiovascular events, such as stroke, angina and myocardial infarction will also be extracted from the HSD for each patient.

The number and classes of antihypertensive medications will also be retrieved for each patient. Global cardiovascular risk will be calculated for each subject by various calculators including the Framingham, the Heart Score, and the INDANA. Follow-up will be about 5-7 years.

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome measure**

Death (any cause)

**Secondary outcome measures**

1. Survival free of cardiovascular events
2. Survival free of renal event
3. Accuracy of different risk calculators in predicting outcome

**Overall study start date**

01/01/2003

**Completion date**

31/12/2011

**Eligibility****Key inclusion criteria**

Italian general population followed in primary care

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

70,000

**Key exclusion criteria**

Subjects in whom serum creatinine measurement is not available

**Date of first enrolment**

01/01/2003

**Date of final enrolment**

31/12/2011

# Locations

## Countries of recruitment

Italy

## Study participating centre

Rettorato Università di Genova

Genova

Italy

16100

# Sponsor information

## Organisation

Carige Foundation (Fondazione Carige [Cassa di Risparmio di Genova e Imperia]) (Italy)

## Sponsor details

Via G. D'Annunzio 15

16100

Genova

Genova

Italy

16100

## Sponsor type

Charity

## ROR

<https://ror.org/03c79xe68>

# Funder(s)

## Funder type

Charity

## Funder Name

Carige Foundation (Fondazione Carige [Cassa di Risparmio di Genova e Imperia]) (Italy)

# Results and Publications

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date****Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration