

General Practitioners and Nephrologists for Outpatient Assistance

Submission date 16/01/2010	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 18/02/2010	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 18/02/2010	Condition category Urological and Genital Diseases	☐ Individual participant data
		☐ 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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Additional identifiers

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.

Primary study design

Observational

Study design

Retrospective analysis and observational prospective study

Study type(s)

Other

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(s)

Death (any cause)

Key secondary outcome(s)

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

Completion date

31/12/2011

Eligibility

Key inclusion criteria

Italian general population followed in primary care

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration