LifeLines: the pilot study

Published: 26-10-2006
Last updated: 09-05-2024

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Coronary artery disorders
Study type	Observational invasive

Summary

ID

NL-OMON29786

Source
ToetsingOnline

Brief title
LifeLines

Condition

- Coronary artery disorders
- Anxiety disorders and symptoms
- Bronchial disorders (excl neoplasms)

Synonym
diseases with more than one cause, multifactorial diseases

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W,de Samenwerkende Noordelijke Provincien;de Nierstichting;het Diabetesfonds Nederland;het UMCG en de RUG

Intervention

Keyword: aging, biobank, disease, genetics

Outcome measures

Primary outcome

The process of invitation and the response of participants and the data collection will be registered and measured. Time spent during visits will be recorded. Extra questions are added to the questionnaires regarding participant motivation and experiences during the study. The collection and handling of blood and urine samples will be tested so that necessary adjustments can be made for the main study.

The main study will investigate the development of a disease related to ageing, psychopathology, cardiovascular, renal, metabolic, endocinological or pumonary disease or a musculoskeletal disorder.

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Secondary outcome

The burden of disease for the society in terms of care needed (this is part of the main study).

Study description

Background summary

Multifactorial diseases are by definition the result of multiple risk factors that are both genetically and environmentally determined. Examples of multifactorial diseases are depression, COPD, cancer, cardiovascular and endocrine diseases. Together they comprise the most common disorders in

adulthood and are responsible for the use of the majority of health care resources. Biomedical and epidemiological research on the etiology of multifactorial diseases frequently focuses on single determinant - outcome relations, without taking into account other risk factors, other diseases and time dependent effects. This has been recognized over the last years and resulted in new study designs sometimes referred to as *life course epidemiology*.
Multifactorial diseases may have more in common than generally recognized, since some risk factors are associated with multiple diseases, as has been shown for example by low birth weight. A risk factor like smoking results in lung cancer in some individuals and myocardial infarction in others, whereas it has a protective effect on dementia, suggesting an individual susceptibility for specific risk factors. The individual differences that determine which disease occurs in the presence of a given risk factor are called modifiers. Since different diseases share identical risk factors, it is clear that a continuing exclusive focus on associations between single risk factors and single outcomes will not unravel the unresolved issues of etiology and individual prognosis of multifactorial diseases. Instead, research has to focus on the underlying mechanisms why individuals with similar (established) risk factors develop different diseases, i.e. the modification of the universal risk factors for multiple disorders.

Study objective

The aim of the pilot study is to study the logistics of inviting, interviewing and examining 2000 participants from general practices in Sneek, The Netherlands. More specifically, to test the invitation procedure, the visiting schedule, the measurements, and the amount of time necessary per participant to complete the visits. Also, the equipment and data storage thereof will be tested. Moreover, a database is created which can also be used for the main study , and during the pilot study, the use of electronic questionnaires will be tested. Blood and urine will be collected, and the process of collection, transportation to the laboratory and analysis and storage will be tested as well. Samples will be handled the same way as in the main study and can later be used in the main study.

Study design

LifeLines is an observational follow-up study in a large sample of the population of the northern provinces of the Netherlands. A random sample of persons between 25 and 50 years of age will be invited by their general practitioner to participate in the study. Data will be collected and on grounds of the results of this pilot study, the data collection process in the main study will be adjusted. The study population in the main study will be followed for 30 years, with an investigation of the population every 3 to 5 years. Methods of data collection are matched with other ongoing biobank studies (P3G

consortium), which enables combining datasets to construct large study populations.

Study burden and risks

Participants of the study will have to fill in several questionnaires, and furthermore their length, weight, waist and hip circumferences and blood pressure will be measured. Their pulmonary function will be tested, an ECG performed, as well as two psychological tests. Also, we will ask them to collect urine, and have a blood sample taken. The main results of these tests will be sent to the participants and their general practitioner, so that measures can be taken if necessary. Except for the venapuncture there are no risks involved. Information on DNA tests will not be revealed to participants and general practitioners.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Patients registered in a general practice in Sneek, The Netherlands, between 25 and 50 years of age.

Exclusion criteria

Severe psychiatric or physical illness, which makes participation in a broad study unfavourable, e.g. a terminal illness.
Not being able to understand the Dutch language.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-11-2006
Enrollment:	2000
Type:	Actual

Ethics review

Approved WMO

Date:	26-10-2006
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL13385.042.06