Leiden Longevity Study follow-up study

Published: 30-08-2021
Last updated: 30-11-2024

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Ethical review	Approved WMO
Status	Completed
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON52307

Source
ToetsingOnline

Brief title
LLS follow-up study

Condition

- Other condition

Synonym
ageing, healthy ageing

Health condition

veroudering, cardio-metabole gezondheid, darmgezondheid, cognitie en leeftijdsgerelateerde ziektes

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,75.000 euro door

ZonMw

Intervention

Keyword: ageing, biomarkers, healthy ageing

Outcome measures

Primary outcome

We will investigate changes in cardio-metabolic, cognitive, and physical performance over time and obtain novel biomarker in this follow up study.

Phenotypic characteristics to be collected:

Cardio-metabolic measurements

o (1H NMR based) Nightingale metabolomics

o Blood pressure

o Body composition (Bioelectrical impedance analysis (BIA))

o Heart rate and heart rate variability (Electrocardiogram (ECG) (novel at follow-up))

Cognitive function

o Attention (Stroop colour word test)

o Processing speed (Digit Symbol Substitution Test (DSST))

o Memory (15-Picture learning test (PWL))

o Global cognitive function (Mini-Mental State Examination (MMSE) (novel at follow-up))

o Language (Animal fluency (novel at follow-up))

o Subjective memory complaints (novel at follow-up)

Physical performance

o Hand grip strength

o Short Physical Performance Battery (SPPB)

o Activities of Daily Living (ADL) and Instrumental Activities of Daily Living

(IADL) questionnaires (novel at follow-up)

Gut health (novel at follow-up):

o Stool sample to perform gut microbiome 16S measurements

o Questionnaire on stool sample and Bristol Stool Chart

o Gastrointestinal symptom rating scale (GSRS) questionnaire

Habitual dietary intake

o Food Frequency Questionnaire (FFQ)

Physical activity

o Short QUestionnaire to ASsess Health-enhancing physical activity (SQUASH)

(novel at follow-up)

Anthropometric measurements

o Heigth

o Weight

o Hip and waist circumference

Mood, depression, apathy, and quality of life

o Several general questions on well-being

o Center for Epidemiological Studies Depression Scale (CES-D)

o EuroQol five dimensions questionnaire (EQ-5D-3L) (novel at follow-up)

o EQ-VAS (novel at follow-up)

Medication use

o List from pharmacy

o Check of the pharmacy list with participant

Medical history

o List from GP

o Check of the GP list with participant

General questionnaire on marital status, occupation, education, alcohol use,

smoking, self-rated health, and sleep.

Secondary outcome

NA

Study description

Background summary

The Leiden Longevity Study was initiated in 2002, in which a total of 421 families were enrolled based on their extreme longevity, defined by the presence of two living siblings including men >89 years and women >91 years (generation F1). The aim is to study the genetic determination of human

longevity and disease in old age. Moreover, the offspring (N=1,750) of these long-lived siblings and their current partners (N=776) were recruited (generation F2) to study phenotypic characteristics of longevity and physiological mechanisms protecting from disease. We are now planning a new follow-up study, 19 years after initiating the Leiden Longevity Study, and include a selection of the F2 generation, who were aged 60 years on average at inclusion. Since we already have a rich dataset of (genotypic and) phenotypic characteristics of the F2 generation from 19 years ago and for some participants also from 13-15 and/or 11-12 years ago, we primarily aim to investigate differences in phenotypic changes over time in these individuals (e.g. physical and cognitive performance) and relate these to health biomarkers generated from baseline measurements and the changes in these biomarkers over time.

Study objective

We aim to study individual changes in phenotypic characteristics of cardio-metabolic health, and of cognitive and physical performance over a time span of 11 to 19 years in older individuals previously included in the Leiden Longevity Study. This allows us to establish individual age trajectories of the phenotypic characteristics where in the past we only used observations of single timepoints. Due to the rich baseline data we will be able to study whether baseline health markers (genetic traditional clinical variables as well as novel biomarker algorithms based on genetics, metabolomics and DNA methylation) predict any or all of the phenotypic changes and whether we can improve these algorithms. We will
1) establish the variability of change in these phenotypic characteristics over time and to what extend these associate with each other;
2) establish whether such phenotypic changes associate with variation in biomarker levels, such as those of gut health, to be measured in this follow up study;
3) establish whether novel biomarker algorithms constructed from variables measured at baseline and/or across different timepoints associate to the phenotypic changes and/or to gut health;
4) establish whether these changes over time depend on longevity propensity by comparing offspring of long-lived families and their partners;
5) establish the relation of phenotypic changes to future mortality and (co)morbidity.

Study design

This study is an observational nested case-control family-based follow-up study which includes a selection of 500 participants, consisting of members of a family enriched for longevity (cases) and their partners (controls). This study consists of questionnaires and collecting biomaterials at home and phenotypic measurements at the research center.

Study burden and risks

There are no direct benefits to the subjects. We ask the participants to collect a sample of their urine and stool, which may be of some discomfort. We include some questionnaires about well-being, anxiety, and depression, which might be experienced as burdensome for some participants. There is one visit to the research center of approximately three hours. Blood withdrawal of 8 tubes with in total 64.5 mL will be performed, which is a minimally invasive procedure. Cognitive tests might be confronting for some of the participants.

Contacts

Public
Leids Universitair Medisch Centrum

Einthovenweg 20
Leiden 2333 ZC
NL
Scientific
Leids Universitair Medisch Centrum

Einthovenweg 20
Leiden 2333 ZC
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Participated in the first wave of the Leiden Longevity Study in 2002, with at least a baseline blood sample present and preferably participated in the third round of the LLS in 2009-2010, or in at least one other follow-up study of the LLS
- Able to give written informed consent
- Willing and able to visit the research centre in Leiden with public or private transport
- Willing and able to follow the study protocol

Exclusion criteria

- Not able to give written informed consent
- Not able to visit the research center in Leiden with public or private transport
- Not able to follow the study protocol

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	01-11-2021
Enrollment:	500
Type:	Actual

Ethics review

Approved WMO

Date:	30-08-2021
Application type:	First submission

Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	10-06-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	13-06-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL77008.058.21