Studying the variation of "biological age" in a healthy population

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To study the variation of biological age within and between different chronological age categories using forced expiratory volume in 1 second (FEV1), systolic blood pressure, clinical chemistry and epigenetic tests in blood samples of healthy...

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

Summary

ID

NL-OMON43110

Source
ToetsingOnline

Brief title
Biological age in healthy individuals

Condition

- Other condition

Synonym
Biological age, Biomarker profiling

Health condition

Explorative research on age related disease specific biomarkers as endpoints in (pharmacological) intervention studies.

Research involving
Human

Sponsors and support

Primary sponsor: Janssen Prevention Center
Source(s) of monetary or material Support: Janssen Prevention Center;Leiden

Intervention

Keyword: Aging, Biomarker, Epigenetics, Variability

Outcome measures

Primary outcome

The biological age will be estimated across different chronological age categories using biological age parameters including FEV1, systolic blood pressure, clinical chemistry parameters and epigenetic tests. For all clinical chemistry parameters (except glycated haemoglobin), different sample matrices (frozen serum versus frozen plasma) will be obtained and results will be compared. For some of these parameters, different laboratories will be compared. Overall the following aging parameters will be analysed:

1. Physical parameters: FEV1 and systolic blood pressure.

2. Clinical chemistry: total cholesterol, C-reactive protein (CRP), cytomegalovirus IgG, creatinine, urea nitrogen, alkaline phosphatase, albumin, glycated haemoglobin, alpha-1-acid glycoprotein, citrate, ceruloplasmin, haptoglobin, alpha-1-antitrypsin, IL-6,IL-18, IL-1*, TNF*, IGF-1, estradiol and dehydroepiandrosterone (DHEAS).

3. Epigenetic markers: DNA methylation age and aging-related microRNAs.

Secondary outcome

Remaining blood samples may be used for disease-specific markers and exploratory analyses. Disease-specific markers for Alzheimer*s disease may

include: total concentration of anti-(phospho-)tau antibodies, (phospho-)tau concentration, *-amyloid concentration, Herpes Simplex Virus IgG and IgM and Alzheimer*s disease-related microRNAs. Exploratory analyses may include: additional aging parameters (e.g. telomere length, transcriptomic age, other aging and/or tissue-related differential DNA methylation, other aging-related differentially expressed (non-coding) RNAs including microRNAs, other acute phase proteins, VLDL particle size and other metabolomics parameters), other disease*specific parameters (e.g. cardiovascular biomarkers), long-term sample stability testing (up to 15 years) or bridging to state of the art methodologies. Determination of additional parameters in already collected materials, which are in agreement with the study objectives and do not provide prognostic or genetic information, will be communicated with the Ethics Committee by means of a non-substantial amendment.

Study description

Background summary

The incidence of age-related disease like Alzheimer*s disease, prostate cancer and cardiovascular diseases increases significantly with age and therefore aging is an important factor when studying these diseases. In future studies, the Janssen Prevention Center of Crucell Holland BV, part of the Janssen Pharmaceutical Companies of Johnson & Johnson, herein forth mentioned as the Janssen Prevention Center intends to study the variation of biological age in relation to disease-specific markers for the estimation of disease risk.

Study objective

To study the variation of biological age within and between different chronological age categories using forced expiratory volume in 1 second (FEV1), systolic blood pressure, clinical chemistry and epigenetic tests in blood

samples of healthy subjects.

Study design

This is an exploratory cross-sectional study which will be executed at the Centre for Human Drug Research (CHDR) in Leiden. A total of 60 healthy volunteers will participate: 20 subjects aged between 20 and 30 years, 20 subjects aged between 40 and 50 years and 20 subjects aged between 60 and 70 years. Of the participating subjects 50% needs to be women and 50% men within each age category

Study burden and risks

This study requires physical examination, vital signs, FEV1, and collection of blood and urine samples. The burden for the volunteer related to the study procedures is limited. All collections will be performed in a state of the art clinical unit and medically supervised by qualified medical staff.

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

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
1. Healthy male and female volunteers aged 20 * 30 years (including 30), or 40 * 50 (including 50), or 60 * 70 (including 70). Healthy status is defined by absence of evidence of any active or chronic disease following a detailed medical history and a complete physical examination including urinalysis.
2. Body Mass Index (BMI) below 30 kg/m².
3. Ability to communicate well with the investigator in the Dutch language.
4. Able to give written informed consent and willing to comply with all study-related procedures, and have signed an informed consent prior to any study-mandated procedure.

Exclusion criteria

Eligible subjects must meet none of the following exclusion criteria on the study day:;1. Are pregnant (positive pregnancy test) or lactating.
2. Taking any prescription drugs within 14 days of the study day or within 5 times the elimination half-life of the medication (whichever is longer), except female subjects who use contraceptives. Occasional acetaminophen/paracetamol is allowed. Exceptions may apply when, judged by the investigator, use of concomitant medication does not interfere with the study objectives.
3. Currently have, or have history of, clinically significant pulmonary, cardiovascular, endocrine, hematologic, neurological, immune, gastrointestinal or genitourinary disease or cancer.
4. Have had significant acute infection within two weeks of the study day.
5. Positive test for drugs of abuse and/or positive alcohol test on the study day .
6. Have a history of alcohol and/or drug abuse.
7. Smoking more than 5 cigarettes or equivalent per day in the past 6 months prior to the study day and unable to abstain from smoking whilst in the unit.
8. Donation or loss of blood over 500 mL within three months (males) or four months (females) days prior to the study day.
9. Have any dermatological condition (including eczema, skin disease at vein puncture site, keloids or scarring) that, in the opinion of the investigator, could increase the risk of adverse events to the volunteer from the sampling procedure.
10. Participation in a clinical trial within 90 days of the study day or more than 4 times in the previous year.
11. Have had prior unforeseen (serious) adverse reactions to blood donation including

fainting, angina, severe bruising, scarring, allergic reactions, or any other adverse events.
12. Not having a general practitioner.
13. Have any physical or psychological medical condition which, in the opinion of the investigator, would be a contraindication to participate.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-04-2016
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	25-04-2016
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

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	NL57181.056.16