Urimon, study of blood and urine for health monitoring

Published: 16-01-2019
Last updated: 12-04-2024

The goals of the Urimon study is to test the hypothesis that microRNA expression profiles in periodic urine- and blood samples from individuals can be used for the sensitive detection of the onset of disease.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Cardiac disorders, signs and symptoms NEC
Study type	Observational non invasive

Summary

ID

NL-OMON54711

Source
ToetsingOnline

Brief title
Urimon

Condition

- Cardiac disorders, signs and symptoms NEC
- Miscellaneous and site unspecified neoplasms malignant and unspecified
- Cranial nerve disorders (excl neoplasms)

Synonym
cancer, cardiovascular diseases, nervous system diseases

Research involving
Human

Sponsors and support

Primary sponsor: You2Yourself
Source(s) of monetary or material Support: You2Yourself BV financiert het onderzoek

Intervention

Keyword: Biomarkers, Blood, Early detection of disease, Urine

Outcome measures

Primary outcome

• microRNA profiles derived from NGS of the small RNA fractions of blood and urine.

• Sets of differentially expressed microRNAs in samples from people that developed high-incidence forms of cancer or cardiovascular disease.

• Longitudinal expression patterns of disease associated microRNAs in sample series from individuals that developed these diseases.

Secondary outcome

NA

Study description

Background summary

Urimon is a study in which it will be investigated if it is possible to perform health monitoring by periodic profiling of microRNA expression levels in urine and/or blood samples.The hypothesis is that diseases including cancer, cardiovascular diseases and neurodegenerative disease can be detected in an early stage this way, before physical complaints become apparent. This hypothesis is based on the fact that microRNA expression profiles in blood and urine are relatively stable in healthy individuals. This indicates that alterations in the expression of diagnostic microRNAs will be picked up more sensitively when measurements are compared to a baseline determined at health than if they are compared to the average expression level of the microRNA's in a larger population (as is the current practice in of disease detection). For most forms of cancer and the main cardiovascular diseases, multiple diagnostic micro RNAs have been found in blood. Also in urine diagnostic microRNAs have been found for multiple types of cancer and cardiovascular diseases. The alterations in expression levels of these microRNAs can be caused by alterations in diseased cells, by tissue damage in affected organs or by

activation of the immune system. The expectation, based on this knowledge, is that the onset of disease in an individual will result in alterations in microRNA profiles that can signal disease and can specify which disease is occurring. To what extent alterations in microRNA profiles will overlap in different persons with the same disease, or in different diseases in the same person cannot be predicted. This will become clear in the Urimon study.

Study objective

The goals of the Urimon study is to test the hypothesis that microRNA expression profiles in periodic urine- and blood samples from individuals can be used for the sensitive detection of the onset of disease.

Study design

To acquire sufficient disease-onset-containing sample series we will collect 3-monthly urine (obligatory for participation) and yearly blood (facultative) samples from at least 11.000 donors that are healthy and between 45 and 75 years of age at the start of the study, which we will follow for 2 years. Baed on historical incedence rates, 7% of these people will developed a serious disease (cancer, cardiovascular disease, neurological disorder). We will test the hypothesis by determining the microRNA expression profiles, by Next Generation Sequencing, in the urine and blood samples that were collected prior to the diagnosis of disease. We will analyse sample series of all ~230 donors that developed cancer, 230 that developed cardiovascular disease, all donors (~40) that developed neurological disorder and 230 controls that remained healthy over the 2 year course of sample donation.

Study burden and risks

There are no known risks or adverse effects to urine sample collection or filling out a questionnaire. There are some known risks or adverse effects to blood sample collection like hematoma which can cause discomfort and pain. There will be 8 times of urien collection and 9 times to fill out the questionnaire. Blood will be drawn twice if a participant is willing. The overall burden for subjects is low in this study.

There is no direct benefit of this study for the participants. The future benefit for the population could be the development of a health monitoring method that enables early detection of disease, allowing earlier and less burdening treatment while increasing chances of cure and leading to lower costs for society.

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

normal health, between 45 and 75 years of age
people with a known predisposition for diseases of interest between 30 and 75 years of age

Exclusion criteria

currently suffering from a form of cancer, cardiovascular disease or neurodegenerative disease

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	03-04-2019
Enrollment:	11000
Type:	Actual

Ethics review

Approved WMO

Date:	16-01-2019
Application type:	First submission
Review commission:	METC NedMec

Approved WMO

Date:	03-07-2019
Application type:	Amendment
Review commission:	METC NedMec

Approved WMO

Date:	08-01-2020
Application type:	Amendment
Review commission:	METC NedMec

Approved WMO

Date:	13-05-2020
Application type:	Amendment
Review commission:	METC NedMec

Approved WMO

Date:	08-01-2021
Application type:	Amendment
Review commission:	METC NedMec
Not approved	
Date:	15-01-2021
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO	
Date:	07-09-2022
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO	
Date:	30-03-2023
Application type:	Amendment
Review commission:	METC NedMec

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	NL67854.041.18