Biomarkers of health in exhaled breath of elderly people- a pilot study

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal motility and defaecation conditions
Study type	Observational non invasive

Summary

ID

NL-OMON45259

Source
ToetsingOnline

Brief title
Breath study

Condition

- Gastrointestinal motility and defaecation conditions
- Glucose metabolism disorders (incl diabetes mellitus)
- Bronchial disorders (excl neoplasms)

Synonym
asthma en irritable bowel syndrome), specific health complaints (diabetes mellitus type 2

Research involving
Human

Sponsors and support

Primary sponsor: Food and Biobased Research-Wageningen University & Research
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Breath analyses, Proton Transfer Reaction Quadrupole ion Time Of Flight (PTR-QiTOF), Seniors

Outcome measures

Primary outcome

Degree of differentiation between biomarkers in seniors who either have no

specific health complaints, or who suffer from either diabetes mellitus type 2,

asthma, or irritable bowel syndrome.

Secondary outcome

Degree of association between the amount of measured biomarker and the severity

of the specific health complaints.

Study description

Background summary

Increasingly biomarkers are being used as health indicators in humans. Biomarkerstudies focus especially on the monitoring and prediction of health of specific popiulations or of individuals with specific health risks. Most often these biomarkers are measured invasively in blood, but recently markers are also measured non-invasively in exhaled breath. This has advantages, especially for use in groups such as children or (frail) elderly. Most often breath analysis uses sampling based on GC-MS, which facilitates off-line sampling but is prone to measurement error. In a new development - the PTR-QiTOF- exhaled breath is directly sampled by the analysis equipment which should result in lower measurement errors. Pilot studies with the PTR-QiTOF have been carried out by the applicants with healthy participants . Research protocols have been developed based on the results of these pilot studies, and these will be applied in future studies such as the one proposed here.

Study objective

The objective of the study is to determine whether the new PTR-QiTOF method can successfully differentiate between seniors without specific health complaints and those who suffer from diabetes mellitus type 2, asthma, or irritable bowel

syndrom. Previous research identified breath biomarkers for diabetes mellitus type 2, asthma, and irritable bowel syndrome by GC-MS analyses. We hypothesise that these (and possible additional) biomarkers can be more easily identified using PTR-QiTOF thus confirming the association between these biomarkers and these specific health problems in elderly.

Study design

The study design will be a within-subject design with repeated measures and a duration of four months. Four groups of seniors will be included in the study: seniors with diagnosed type 2 diabetes, asthma, or irritable bowel syndrome and healthy controls (25 participants per group). Participants visit the lab once per month for breath analysis and to fill out a short questionnaire (appr. 15 minutes). In addition, participants fill out a digital questionnaire on disease-specific complaints (type and severity, duration 10 minutes) from home on a weekly basis.

Study burden and risks

The risks of this study are very low because participants are only required to breath a number of times in a tube (6 times 5 seconds per visit). The burden consists of monthly visits to the lab (20 minutes per visit) over a period of five months for breath analysis and to fill out a short questionnaire. In additon, participants fill out a digital questionnaire on disease-specific complaints on a weekly basis from home.

Contacts

Public
Food and Biobased Research-Wageningen University & Research

Bornse Weilanden 9
Wageningen 6708 QG
NL
Scientific
Food and Biobased Research-Wageningen University & Research

Bornse Weilanden 9
Wageningen 6708 QG
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Participants in all four groups must meet all of the following criteria:
* They have signed the informed consent
* They are * 55 years old
* They are able and willing to visit the RIKILT lab facilities on a monthly basis (5 times in total).
* They have a desktop or laptop with internet access at home ;Additional inclusion criteria per experimental subgroup (based on self reported information)
* Diabetes mellitus type 2: formal diagnosis by a medical doctor
* Asthma: formal diagnosis by a medical doctor , no exercise-induced asthma, prescribed medication use during the last month
* Irritable bowel syndrom: formal diagnosis by a medical doctor and complaints during past month

Exclusion criteria

* Smokers
* People who suffer from more than one of the conditions of interest, diabetes type 2, asthma and/or irritable bowel syndrom

Study design

Design

Study type: Observational non invasive

Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-05-2017
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	05-04-2017
Application type:	First submission
Review commission:	METC Wageningen Universiteit (Wageningen)

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	NL58299.081.16