Diagnostic tests in non-invasively acquired body fluids

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To investigate whether sweat, tear fluid, saliva and fingermarks can be used as diagnostic tool by determining whether a relation can be found between blood levels and levels found in the four investigated fluids (primary interest: PSA levels,...

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

Summary

ID

NL-OMON53111

Source
ToetsingOnline

Brief title
Diagnostic tests in body fluids

Condition

- Other condition

Synonym
Diagnostic tests, Medical examinations

Health condition

diagnostische bepalingen

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: diagnostisch bepalingen, lichaamsstoffen, niet-invasief, speeksel, traanvocht, vingerafdrukken, zweet

Outcome measures

Primary outcome

- to demonstrate the presence of a compound of interest in blood and sweat,

tear fluid, saliva and fingermarks.

- to determine the amount/levels of that particular compound in blood and

sweat, tear fluid, saliva and fingermarks.

- to investigate whether a relation can be found in the levels of a particular

compound in blood and sweat, tear fluid, saliva and fingermarks.

In this study we start with investigating the PSA levels, hormone levels and

blood group typing.

Secondary outcome

na

Study description

Background summary

Diagnostic tests are performed to aid in diagnosis or/and detection of diseases. In most cases, blood, urine and faeces will be studied on the presence of certain deviations. Blood draws are an invasive medical treatment and can cause emotional distress and varying degrees of pain.

If a non-invasive method is available that can be used for diagnostic testing, it will be a great advance in the medical field. In this study we want to investigate whether it is possible to use non-invasively acquired body fluids as diagnostic tool, including sweat, tear fluid, saliva and fingermarks. We hypothesize that the chemical composition of the four fluids are related to the chemical composition of blood. If this is true, diagnostic tests can be performed in these non-invasively acquired body fluids instead of blood.

In a small pilot-study, we investigated the possibilities of using fingermarks as a diagnostic tool. We were able to detect PSA, LH and FSH in fingermarks. Also, the blood group type could correctly be determined in fingermarks of donors of which the blood group type was known.

In this study we want to investigate whether a relation can be found between blood levels and levels found in sweat, tear fluid, saliva and fingermarks. To these four fluids as a diagnostic tool, not only the presence of a certain component, but also the amount of that component is of importance. Blood levels will be determined using the standard method (LAKC). The blood levels will be compared with the levels found in sweat, tear fluid, saliva and/or fingermarks. Since we already know that it is possible to detect PSA and the blood group type in fingermarks, we want to start this study with determining whether there is a relation between PSA, FSH, LH, testosteron, IgE and IgG levels and blood group antigens found in the different fluids, compared to the levels found in blood. If a relation can be found between PSA levels, hormone levels in blood and the non-invasively acquired body fluids, we want to expand this study, by testing also other important and standard diagnostic tests.

If sweat, tear fluid, saliva and/or fingermarks can be used as non-invasive method for diagnostic testing, it will be of a major impact to the medical field.

Study objective

To investigate whether sweat, tear fluid, saliva and fingermarks can be used as diagnostic tool by determining whether a relation can be found between blood levels and levels found in the four investigated fluids (primary interest: PSA levels, hormone levels and bloodgroup typing).

Study design

Observational study.

Study burden and risks

The nature of the burden is classified as minimal, considering that subjects have to donate blood (minimum 1 tube of 5ml, maximum 3 tubes with a total of

15ml). There are no risks.

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

Inclusion criteria for healthy volunteers:
18 years or older and mentally competent.
Inclusion criteria for unhealthy volunteers, they must meet one of the following criteria:
-Having a disease, systemic, metabolic.
-Psyhiatric, somatic, organic or neurological disorder.
-Use of medication which might effect the immune system
-Known to have abnormal blood values

Exclusion criteria

Healthy volunteers: exclusion criteria:
- Younger than 18 years and mentally incompetent.
-Pregnancy, or presumption of pregnancy
-The use of anticoagulants or having coagulation disorder
-Use of any investigational drug
-Use of somatic medication which may affect the immune system
-Current or recent (<1 year) alcohol or substance abuse
-Current psychiatric disorder or a first degree family member with a major psychiatric disorder
-Current systemic disease
-Major metabolic disease
-Somatic, organic or neurological disorder, Exclusion criteria unhealthy volunteers:
- 18 years or younger
- mentally incompetent.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	08-07-2015
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	26-02-2015

Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-07-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL44989.018.13