Determination of biological variation of several special clinical chemical tests

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1; determination of biological variation of special clinical chemical measurements2: determination of reference values of a.o. Factor VIII, XI, XII and future measurements

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

Summary

ID

NL-OMON35475

Source
ToetsingOnline

Brief title
biological variation

Condition

- Other condition

Synonym
nvt

Health condition

diverse klinisch chemische bepalingen op het gebied van voedingsstatus, geneesmiddel metabolisme, tumormerkers, botmetabolisme, stolling, immuniteit, biogene aminen en hormonen

Research involving
Human

Sponsors and support

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

Intervention

Keyword: biological variation, critical diffference, healthy subjects, homeostatic setpoint

Outcome measures

Primary outcome

Biological variation of

TPMT phenotyping

Factor VIII, XI, XII

RBC fatty acid composition

plasma carotenoids

tryptophan/kynurenin

vitamin D

testosteron

metanephrines

methylmalonic acid

complement

IgG1-4

C1esterase inhbitor

calcitonine

S100

IgD

growth hormone

inhibin

PSA/free PSA

lysozyme

C3d

Secondary outcome

n.v.t.

Study description

Background summary

The result of a laboratory measurement is influenced by analytical variation, biological variation and pathophysiological circumstances. The differences between 2 consecutive measurements (eg by follow up of patients) is determined by many factors, including treatment, and at least analytical and biological variation (within subject). It is important to determine the biological variation to be able to determine the reference change value. In addition, biological variation determines the desired analytical variation. The reference change value is important in establishing whether two results differ significantly. In addition, biological variation is important to estimate the variation around the homeostatic setpoint of an individual. In case of large variation, a single measurement does not provide information regarding the homeostatic setpoint of an individual subject. Together, the analytical and biological variation determine the number of samples that is necessary to estimate the homeostatic setpoint of an individual. In addition, biological variation can be used to establish the *index of individuality* , that indicates the usefulness of reference values of laboratory tests.
Biological variation can be devided in intra individual (within subject) and interindividual (between subjects). The first is important in follow-up of patients.
Many data on biological variation of routine clinical chemical measurements can be found in the Westgard database, (www.westgard.com/biodatabase1.htm). However, this database is not complete and does not include data that will be investigated in this project.
Guidelines are presenty for the establishment of biological variation (1). It is important that the subjects are healthy, to minimalize the influence of pathophysiology. Subjects are not to change their diet, and other lifestyle factors during the study, and medication, except pain killers, should be avoided.

Samples should be collected under comparable conditions and stored appropriately and immediately. To minimalize the contribution of analytical variation, the samples should be analyzed in duplo within 1 series and with a tracable method, if possible. The determination in duplo is neccessary to establish analytical variation and accordingly the biological variation
Some of the laboratory parameters have cut-off values, eg RBC-DHA+EPA >8 g; (2) and vitamin D. Some of the included parameters need the establishment of reference values. Thus, the samples are also used for the determination of reference values.It should be noted that some of the parameters are tumor markers (PSA, free PSA, S100).

Study objective

1; determination of biological variation of special clinical chemical measurements
2: determination of reference values of a.o. Factor VIII, XI, XII and future measurements

Study design

Blood of 30 healthy subjects will be collected using venapuncture during 5 occasions, separated by 4 weeks and during 4 months

Study burden and risks

Burden: filling out questionnaires, venapuncture with included risk (hematome), loss of 3 times 28 ml and
2 times 48 ml of blood. blood pressure measurement
Risk: discomfort resulting from hematoma.

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

apparently healthy men and women 18-65 years old

Exclusion criteria

smoking, pregnancy, any disease or medication use

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-01-2011
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	15-12-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL38389.042.11