What is the distribution of desmosine in serum in healthy subjects and patients with lung disease?

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This study aims to determine the normal distribution of desmosine in a healthy population and a population of patients with COPD (ranging from GOLD I-IV). In addition, the inter-day variation and the correlation with 24-hour urinary desmosine will...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bronchial disorders (excl neoplasms)
Study type	Observational invasive

Summary

ID

NL-OMON36180

Source
ToetsingOnline

Brief title
Distribution of serum desmosine

Condition

- Bronchial disorders (excl neoplasms)

Synonym
chronic bronchitis, COPD

Research involving
Human

Sponsors and support

Primary sponsor: Canisius Wilhelmina Ziekenhuis Nijmegen
Source(s) of monetary or material Support: GlaxoSmithKline,Maatschap longziekten + beurs GSK

Intervention

Keyword: COPD, Desmosine, Elastine

Outcome measures

Primary outcome

- Normal serum desmosine (DES) ug / L for healthy subjects and patients with

COPD

- Inter-day variation DES

- Correlatie with 24-hour urine DES/ serum DES

Secondary outcome

Difference between healthy smokers and healthy non-smokers

Subgroup analysis GOLD I-IV COPD

Study description

Background summary

Lung function tests has long been an important pillar in lungdisease. Not only is lung function used for diagnostic purpose, but also for estimating the prognosis and evaluating the effect of a specific treatment.
These parameters are far from perfect. They are not always specific or sensitive, and often measure the outcome of a process and not the process itself, namely the development of lung injury.
A search for new parameters hasn't yet yielded a good alternatives. There is a need to develop alternative markers such as bio-markers. Desmosine isodesmosine and are examples of this.

In many lung diseases, the underlying problem is the destruction of alveolar tissue and loss of elasticity. The most common diseases are COPD and pulmonary emphysema. Elastin in the lung is formed by cross linking tropo-elastin (elastin precursor). This process is possible due to (Iso)desmosine. These proteins are exclusively found in elastin. In patients with COPD / emphysema the degradation of elastin stands centrally. This proces happens under the influence of proteases. These proteins are produced by several inflammatory cells (macrophages / neutrophils / T cells). Secondly, there is a

downregulation of the anti-proteases, whitch have a protective role on the pulmonary elastin. The overall result is elastin degradation whitch causes various components in the bloodstream. These includes the (iso) desmosine.

Because lung tissue consist of such a high proportion of elastin, there may be a role for desmosine in pulmonary medicine. This can be diagnostic,to evaluate therapy and its prognosis. To this date Investigations that have taken place, could not give DES a role in daily practice.. This is partly due to the small study populations that have been used and due to the complexity and costliness of the laboratory assessment.
In recent years there is lots of advancement in this field. Mass spectrometry (MS) combined with ultra-pressure liquid chromatography (UPLC), is one of the most interesting develpments. With UP-MS/MS (iso) desmosine can be measured in various body fluids. UP-MS/MS gives a good sensitivity and specificity in the measurement of (iso) desmosine.

In the past mostly desmosine (DES) measurements took place in 24 hour urine. UP-MS/MS allows accurate measurements in the serum. Correlation between 24-hour urine DES and plasma DES has been examined in only a small subgroup. Inter-day variation for 24 hour urine was considered relatively stable with a coefficient of variation of about 8%. This is, however, for plasma DES.

Study objective

This study aims to determine the normal distribution of desmosine in a healthy population and a population of patients with COPD (ranging from GOLD I-IV). In addition, the inter-day variation and the correlation with 24-hour urinary desmosine will be determined.

Study design

Cross sectional descriptive study

Study burden and risks

Hematoma caused by vena puncture in the arm.
Possible pulmonary function testing

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

Control population: adult, mentally competent subjects without pulmonary disease
COPD population: adult, mentally competent patients. (The diagnosis was made **according to GOLD guidelines.).

Exclusion criteria

Control population; pregnancy, pulmonary complaints
COPD population; reversibility in lung function (> 12% and 200ml), recent COPD exacerbation (<3 months before enrollment), pulmonary malignancy, lobectomie/pneumectomie, pregnancy

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-08-2012
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO

Date:	06-03-2012
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL37215.091.11