A comparison of different breath sample collection approaches and its impact on results quality.

Published: 06-10-2014
Last updated: 24-04-2024

To evaluate exhaled breath sampling approaches and their impact on results quality. To establish if sampling procedures impact specificity and sensitivity in extracting information of interest * in our case impact of garlic/fish oil supplements on...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON40341

Source
ToetsingOnline

Brief title
BSCA (Breath Sample Collection Approaches)

Condition

- Other condition

Synonym
no conditions/ disorders - healthy volunteers are included to study and compare breath collection procedures

Health condition

no conditions/ disorders - healthy volunteers are included to study and compare breath collection procedures

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Top Institute Food and Nutrition

Intervention

Keyword: □ Alveolar air, □ Breath Sampling, □ Filtered air, □ Garlic/fishoil

Outcome measures

Primary outcome

Composition of volatile organic compounds present in exhaled breath. Validation

of sampling approaches.

Secondary outcome

-

Study description

Background summary

Analysis of exhaled breath is an exciting and fast developing field of expertise. Many research groups focus nowadays on developing accurate, effective and reproducible techniques to non-invasively diagnose patients with all kinds of disorders. Different methodological approaches associated with this topic may at the end cause a big variation in results as well as wrong associations or conclusions while referring to work of others. Thus, techniques and approaches should be compared to see if they generate relevant differences. One of the issues on which research teams involved in this subject seem to disagree is how to collect breath samples. Since the composition of exhaled breath is influenced endogenously and exogenously many researches are trying to come up with ways to limit exogenous sources of compounds as much as possible. Below different ways of collection approaches are described.
Available literature gives an insight into many different approaches but not in comparing them with each other. A common technique is to collect a background sample of the ambient air at the same time as the subject who has reached equilibrium with the room air donates a breath sample. The alveolar gradient is

then calculated [1, 2, 3]. In this case data interpretation is based on the assumption that equilibrium exists for all VOCs between the body and the ambient air which is not a known fact. Other teams give to theirs subjects a clean air supply to reduce the background [4, 5, 6]. This technique is not only reagent consuming but also compromises the portability of testing apparatus. The issue is also whether dead space air should or should not be separated from alveolar air. Alveolar air collection is thought to be most accurate to characterize processes within the body, giving the best picture of blood born volatiles. There are many techniques proposed to collect alveolar air, very often including self-made equipment prepared for that purpose. Not unified way of collection gives opportunity for creating not comparable results. The issue if subjects should inhale normally through their nose or rather through their mouth while using a nose clip to limit nasal contaminations is another question present in breath research. Collection of mixed air, meaning total breath including dead space air and alveolar air is a technique used by many teams including ours [7,8]. Its simplicity reduces the mistakes introduced by more complex techniques. Beside the fact, that lack of restrictions in a way of exhalation is convenient and patient-friendly, not forced exhalation results in a breath characterized by a normal state and behavior. No stress is induced which can affect processes within the body. Even though there are clear positives of using this approach there is still a lot of discussion if the method is not negligible towards important factors.
All these questions have not been solved so far in the literature and they bring us towards this study. So far the approach of our team is to sample mixed breath (alveolar plus dead space) by exhalation into a 3 L Tedlar bag without any special directives. The contents of the sampling bag is transferred to a stainless steel carbon packed sorption tube which later on is thermally desorbed and analysed using gas chromatography-time-of flight mass spectrometry (TD-GC-tof-MS). Data-pre-processing, data-mining and statistical analysis is used to separate the useful information in the breath samples from the redundant information, thus being a tool that deals with problems that other teams seems to deal with by putting more limitations during collection time.
In this study we intend to compare our sampling methodology with most common used, more strict and complex ways of sampling to determine if the results are different. The research question of the study will be: how garlic/fish oil breath-o-print is extracted when using 4 different methodologies. Data will be analyzed as two class problem, differences between Class 1 and Class 2 will be established, using multilevel-PLS-DA in 4 set-ups * one for each collection approach. The analysis takes into account the paired data structure underlying the cross-over design. In total, 4 different multilevel-PLS-DA classification models will be obtained. For each classification model a set of discriminatory VOCs, sensitivity, specificity and overall correct prediction of Class 1 and Class 2 will be received. Note, that sensitivity, specificity and overall correct prediction will be calculated for the validation set.

Study objective

To evaluate exhaled breath sampling approaches and their impact on results quality. To establish if sampling procedures impact specificity and sensitivity in extracting information of interest * in our case impact of garlic/fish oil supplements on volatile organic compounds composition.

Study design

Randomised, cross-over study. Approximately 50 volunteers will be included in the study and randomly assign to Group 1 or Group 2. Volunteers will be asked to produce up to 4 breath samples using different collection methods. Group 1 will have four samples collected without any prerequisite with regard to diet. Proceeding the sampling session, Group 2 will be asked to consume 2 garlic/fish oil capsules each (1 in the evening a day before the collection and 1 - 3h before the collection will occur). In the successive week Group 1 will have four samples collected after consumption of garlic/fish oil capsules (1 in the evening a day before the collection and 1 - 3h before the collection will occur), while Group 2 will have four samples collected without any prerequisite with regard to diet. For every variation in sampling method this will deliver a series of samples of the same subjects with and without garlic/fish oil supplementation.
The sensitivity and specificity obtained for the four different set-ups determine which methodology performs best.
During 1 week:
Group 1: No garlic/fish oil supplementation *These samples will produce the 'normal' volatile organic compounds profiles.
Group 2.: At 10.00 p.m. of day -1 (prior to collection) and 3h before the collection time on day 0 (collection day) each participant will take one garlic/fish oil capsule.
These samples will show the *garlic/fish oil specific' volatile organic compounds profile.

The following samples will be collected from both groups:
Sample 1: exhalation into a Tedlar bag, no special directions- our present way of collecting
Sample 2: exhalation into a Tedlar bag with a nose clip
Sample 3: exhalation into a Teflon tube connected to a three way valve; the first part of exhaled breath discarded as assumed to be a dead space air (around 150ml of tidal volume) and second part collected into a Tedlar bag as being alveolar air;
Sample 4: same as sample 3 but with a use of nose clip

During 1 week:

The groups switch responsibilities. Samples collected following the same scheme.

Intervention

Subject will be ask to consume 1 capsule of garlic/fish oli in the evening, a day before sample collection and 1 capsule 3h before sample collection.

Study burden and risks

One of the advantages of exhaled breath analysis is its non-invasive and patients/participants friendly nature. In comparison to other diagnostic tools, breath collection is not known to cause troubles even when used for children or sick subjects.
Participation in this study involves breathing in a 3L plastic bag during a few minutes. In total maximally 8 bags will be collected: 4 in week 1 (no supplementation) and 4 in week 2, after garlic/fish oil supplementation. Consumption of garlic/ fish oil it is thought to have a beneficial influence on a health but may cause some discomfort in more sensitive individuals. Since those are only two tablets we do not expect to see this kind of reaction.

Contacts

Public
Academisch Medisch Centrum

Universiteitssingel 50
Maastricht 6229ER
NL
Scientific
Academisch Medisch Centrum

Universiteitssingel 50
Maastricht 6229ER
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

50 non- smoking students (m/v, age 18-25y)in good health recruited from the Maastricht University population.

Exclusion criteria

An exclusion criterion is the daily use of garlic/fish oil supplements, current illnesses which might interfere with the study (e.g. prolonged severe diarrhea), respiratory track diseases

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Other

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	50
Type:	Anticipated

Ethics review

Approved WMO

Date:	06-10-2014
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL46538.068.13