Diagnosing chronic cough with a capsaicin provocation test

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Question: Is it an added value for the patient if there will be a default capsaicin provocation test to diagnose chronic cough?It will be investigated or with the aid of the capsaicin provocation test the diagnosis sensory hyperreactivity (SHR) can...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Bronchial disorders (excl neoplasms)
Study type	Observational non invasive

Summary

ID

NL-OMON41167

Source
ToetsingOnline

Brief title
Capsaicin provocation test

Condition

- Bronchial disorders (excl neoplasms)

Synonym
Sensory hyperreactivity

Research involving
Human

Sponsors and support

Primary sponsor: Orbis Medisch Centrum
Source(s) of monetary or material Support: Afdelingsbudget

Intervention

Keyword: Capsaicin, Cough, Inhale, Provocation

Outcome measures

Primary outcome

All data will be recorded in the pulmonary function laboratory of the Orbis

Medical Center in Sittard.

The variables that are collected during this studyare divided in the dependent

and independent variables. The dependent variables are the number of coughs en

the deposit score for chest pain, haorseness, irritation of the throat, runny

nose, mucus and irritation of the eyes. The independent variables are

concentration inhaled capsaicin, gender and age.

Secondary outcome

Inapplicable

Study description

Background summary

Cough is a common complaint that is often perceived as a nuisance. Epidemiological studies have indicated that chronic cough is very prevalent in the community. Approximately 40% of the population will at some point in life qualify with chronic cough. Cough is called chronic if the symptoms persist for longer than eight weeks. A persistent cough usually indicates an underlying condition that requires a causal treatment.
Real idiopathic cough is rare.

For all causes of cough is a test that the disease can be diagnosed, except for the disease sensory hyperreactivity (SHR). It is important, therefore, to introduce an test to diagnose this condition or to exclude.

There are a couple of studies that are occupied with the capsaicin provocation test to diagnose sensory hyperreactivity. It appears that patients with sensory hyperreactivity do have a higher cough respons on the inhalation of capsaicin than healthy people.
Capsaicin is a harmless and odorless vanilloid, that stimulates mostly the afferent unmyelinated C-fibers of the sensory nervous system by the release of neuropeptide P.

Null hypothesis: The standard execution of a capsaicin provocation test in the diagnosis of unexplained chronic cough in patients is an added value for the patient.

Alternative hypothesis: The standard execution of a capsaicin provocation test in the diagnosis of unexplained chronic cough has no benefit to the patient.

Study objective

Question: Is it an added value for the patient if there will be a default capsaicin provocation test to diagnose chronic cough?

It will be investigated or with the aid of the capsaicin provocation test the diagnosis sensory hyperreactivity (SHR) can be made. SHR is known, but there is no test to actually diagnose it.

This research is a pilot survey. We start with 30 patients who are known on our department. As this study shows that it has an added value for the treatment of chronic cough, we are going to test more patients and over a longer period of time after this study.

If more than 10 subjects will have a positive capsaicin challenge test, it is an added value for diagnosing patients with chronic cough. We are going to expand the study en test more subjects and over a longer period of time .

If fewer than 10 subjects have a positive capsaicin provocation test , it will not be valuable in the diagnosis of patients with chronic cough .

Study design

It is an experimental, quantitative, correlational research.

Two weeks prior to the study, the subjects has to stop with antihistamines.
Two days prior to the study, the subjects has to stop with *2-agonists, anticholinergics and inhaled or oral steroids.

The following information is extracted from the medical records: gender and age.
All subjects undergo the same protocol. The subjects have to inhale different

concentrations of capsaicine, to start with the lowest concentrations and to end with the highest concentration. We don't tell this to the subjects. Also we don't tell them that the result of this research is based on the number of coughs .

The different concentrations of capsaicin are dissolved in 0,9% NaCl. The different concentrations of capsaicin are 0 µmol / liter (pure NaCl), 0,4 µmol / liter, 2,0 µmol / liter and 10,0 µmol / liter.

The values are selected on known values, which have been determined in previous studies. With these values can be determined whether or not a person has the disease SHR. The solutions that are used for this study, shall be made for us.

For the test, a flow / volume test is performed to investigate whether the patients already has a bronchoconstriction before the test. Once the FEV1 is decreased compared to previous visits with 20%, the capsaicin provocation test can not carried out and will possibly tried again later.
For the patients safety there will be performed a flow/volume test after the capsaicin provocation test, even though it has been determined that the inhalation of the capsaicin does not cause bronchoconstriction. There should be a bronchodilator available at all times.

For each concentration, an amount of 2 ml is needed. The flow of the inhalation is 0,25 mL/min with an inhalation time of 4 minutes. The output at each concentration is than 1 mL. The flow of inhalation is determined by an air regulator with an adjustable clock. The nebulizer flow is calibrated by determining the output at different flows. The nebulizer flow has to be 4,3 L/min.

Before and after the inhalation of each concentration of capsaicin, each subject will be ask to choose a deposit score. They have to choose a deposit score for symptoms chest pain, hoarseness, throat irritation, runny nose, mucus and eye irritation on a scale from 0 to 3 (0: no symptoms, 3: severe symptoms).

1. Fill the nebulizer with 2 mL of the first solution , this is pure 0.9% NaCl. Weigh the nebuliser solution
2. Ask the subject to the deposit score as described above
3. Ask the subjects to cough so often as needed and not to talk during and after each inhalation
4. Let the subject take the mouthpiece in their mouth and put the nose plug on their nose
5. Turn the nebulizer to a nebulizer flow of 4.3 L / min and tell the subject to breath on his of her own pace for 4 minutes. Count the nubmer of coughs.
6. Tell the subject after the 4 minutes of inhalating through the mouthpiece to take the mouthpiece out of the mouth en the nose plug off their nose en breath on their own pace for another 4 minutes.
7. Count the number of coughs from the time that the atomization of the

solution starts to the end of step 6, with a totel of eight minutes
8. Weigh the nebulizer. The output should be 1 mL.
9. Ask the subject choose a deposit score for all the symptoms
10. If the number of coughs are above the limit values, the capsaicin challenge is positive. There is no need to go further with the higher concentrations of capsaicin. The limit values are for the concentration of 0,4 µmol/liter 10 coughs, for the concentration of 2,0 µmol/liter 35 coughs and for the concentration 10,0 µmol/liter 55 coughs.
11. Wait between each inhalation minimal 10 minutes before starting with the next inhalation.
12. Fill the nebulizer now with 2 mL of solution 2.
13. Repeat step 2 to step 11.
14. If the number of cough is not higher than the limit value (see table 2), step 13 can be repeated for the next solutions.

Study burden and risks

Time will be the only burden for the subjects. For this test, the subjects need to come back to the hospital for two more times. At the first appointment they can ask some questions about the study and they can return the consent form. This appoinment will take about 30 minutes. The second appointment will take about 60 to 90 minutes. At the second appointment will take place the research itself.

Other studies concluded that this provocation test will entail no risks for the patient.

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

Mentally competent;
18 years and older;
Chronic cough;
Normal long function (FEV1, VC and ratio > 80% of predicted values);
Negative histamine provocation test (max fall FEV1 off 10%);
Non smokers;
No other pulmonary diseases.

Exclusion criteria

Not mentally competent;
No cough;
Other pulmonary diseases;
Post nasal drip;
Gastro-oesofageal reflux;
Deviation on x-ray;
No normal values in long function;
Lung infection in the past eight weeks;
Use of ACE-inhibitor;
Excessive mucus production;
Pregnancy or pregnancy wish;
Breastfeeding.

Study design

Design

Study phase:	2
Study type:	Observational non invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	30
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Capsaicin
Generic name:	Capsaicin
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO

Date:	13-05-2014
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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
EudraCT	EUCTR2014-000738-48-NL
CCMO	NL48297.096.14