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Spirometry and Methacholine Challenge Test (MCT) Information and Consent Form

Purpose:

Lung function testing, known as “spirometry,” is regularly used in medical practice to evaluate the presence, extent, and type of abnormal function of the lungs. It is a safe, reproducible method used in the diagnosis of different lung diseases as well as in the assessment of lung (pulmonary) impairment related to such diseases. More specialized types of lung function and related tests are sometimes also used after spirometry to evaluate specific types of lung diseases.

The methacholine challenge test (MCT), also known as an inhaled bronchoprovocation challenge test, is a diagnostic study to determine if a person has asthma, including the form of asthma known as RADS (reactive airways dysfunction syndrome, aka RADS), lung disorder that can develop after an acute inhalation exposure to a chemical or other substance. The test accurately determines the level of hyper-responsiveness (“irritability”) of the conducting portion of the lungs. It is used in people who have an illness history that suggests they may have asthma but whose symptoms, physical examination findings, lung function tests, and/or response to inhaled asthma medication do not clearly demonstrate they have asthma.

Description:

Spirometry. A lung function test, known as a “spirometry” test, involves a device known as a spirometer which measures the flow rate of air from a maximal, forced expiratory effort.

You will be asked to breathe in as deeply as you can through a tube that you place in your mouth and then forcefully blow out as quickly and completely as possible. You will be asked to do this at least three times, and possibly several more times. Because it is entirely an effort-dependent maneuver, specific instructions on how to perform the expiratory maneuver are provided by the physician prior to conducting this test, and “coaching” during the test is also provided to encourage a maximal effort. Three (3) consistent efforts are required to produce a valid test.

Spirometry is safe and easy to perform. The spirometer uses a disposable cartridge that has a filter to prevent the transfer of any microorganisms (germs—bacteria or viruses) to or from the person taking the test.

Methacholine challenge test. After a baseline spirometry test has been completed, an initial dosage of pure saline is administered by a series of 5 progressively increasing doses of a

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medication, methacholine (trade name Provocholine®), is administered by metered, nebulized (aerosol) inhalation. The methacholine is dissolved in a sterile salt solution (saline) to form a liquid, and then is turned into a mist (aerosol) using compressed air and is administered through a device (nebulizer) that is programmed through an attached computer.

Two minutes after each dose of methacholine has been inhaled, the spirometry test is repeated. After any dose in which the lung function declines significantly (more than 20%) from baseline, the test is stopped and an inhaled bronchodilator “rescue” medication (albuterol, trade name Proventil HFA®) is administered, after which the lung function is measured again. An improvement in lung function after bronchodilator confirms the test is “positive.”

Test Duration:

Spirometry takes 5-10 minutes. A full MCT test, i.e., the baseline spirometry, administration of the saline baseline followed by 5 doses of methacholine and spirometry tests after each, and lastly the administration of albuterol inhaler and final spirometry test, typically takes a maximum of 75 minutes.

Test Interpretation:

A “positive” MCT occurs when there is a 20% decline in lung function with any of the first four dosages. The dose of methacholine that is calculated (extrapolated, by computer) to have produced this 20% decline (the PC20) is reported. The lower the PC20, the higher the degree of airways hyper-responsiveness.

A positive MCT does not absolutely mean a person has asthma, though when correlated with the medical history it provides a strong indication of the diagnosis. A small percentage of people without asthma may have a significant lung function decline in response to the highest (final) dose. These are generally “false positive” results.

People who do not react to methacholine, i.e., who have a “negative” test, have a very low probability that they have (or had) asthma or RADS.

Safety/Risks:

The importance of making an accurate diagnosis of or definitively excluding (“ruling out”) asthma or RADS warrants the need for this test. For diagnostic purposes, the MCT is not administered to people with overt symptoms or signs of asthma (or RADS); only to people with atypical symptoms, signs, or non-diagnostic lung function tests should be tested diagnostically. Both in the medical literature and in Dr. Craner’s many years of experience with administering this test, the MCT is well tolerated, and rarely, if ever, have serious complications from this

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procedure been reported or observed, especially if appropriate indications (test reasons) have been carefully selected and documented. The entire test is administered personally by Dr. Craner in his office. Your vital signs (blood pressure, pulse, respiratory rate) will be monitored several times during the test.

The MCT is conducted so that the risk of a severe asthma attack is minimized. Because the methacholine is given in a series of doses that starts with an extremely low dosage, any reactivity to the methacholine may cause some uncomfortable, asthma-like symptoms or sensations, such as cough, chest tightness, or shortness of breath. If the next dosage causes greater symptoms, and the lung function test confirms that there is an asthmatic response, no further doses are given and the test is “stopped.” These symptoms usually last only briefly (minutes to hours), and are quickly reversed when the bronchodilator (Albuterol) medication is administered. If you are given Albuterol, you may feel lightheaded or jittery for about 30 minutes as a result of inhaling the bronchodilator. This medication might also temporarily increase your pulse rate. You will be checked to see if that happens.

The methacholine solution doses are prepared in advance by Dr. Craner, and are transferred through sterile syringes and filters before being administered to ensure microbiological safety.

Methacholine will not cause an asthmatic reaction in people who do not have asthma. Some people who have conditions (diseases) of the throat or vocal cords, or who react adversely to certain odors, may experience their asthma-like symptoms in response to methacholine and/or the saline mist. The saline has a small amount of preservative (phenol) which has a slight, unpleasant odor that may trigger these responses. In these cases, the lung function test will *not* show a corresponding decline in lung function, even though the symptoms may appear just like an asthma attack. Again, these symptoms generally wear off after minutes to hours, and do not require any additional treatment.

In the very unlikely event that you have a severe asthmatic response, bronchodilator (albuterol), oxygen, and epinephrine are available in the office. If you have symptoms that are worrisome or causing significant respiratory compromise after you leave the office, please call Dr. Craner immediately for further instructions, or proceed to an emergency room (not an urgent care facility) if you are unable to reach Dr. Craner. In such a case, you may be advised to seek medical care at the nearest hospital emergency room. You will be responsible paying for any such medical treatment you may require as a result.

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Contraindications:

MCT is not performed for diagnostic purposes in people with the following conditions:

- Active asthma, or spirometry which clearly demonstrates asthma or low baseline lung function (from any cause)
- Recent heart attack or stroke (3 months), or active coronary artery disease
- Poorly controlled hypertension
- Aortic or cerebral aneurysm
- Recent or active, severe upper or lower respiratory tract infection (up to 6 weeks)
- Usage of asthma or related medications prior to the test (see Preparation, below)

MCT may be performed with caution in the following conditions:

- Equivocal lung function tests and/or response to bronchodilator
- Pregnancy or nursing mothers
- Current treatment for myasthenia gravis
- Use of beta-blocker medication for hypertension, coronary artery disease, or other disease
- Seizure disorder

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Patient Preparation for MCT:

In order to ensure that your MCT is conducted accurately, please follow the following pre-test instructions. Since in some cases it may not be determined whether you will need the MCT until after your examination and baseline spirometry has been completed, please follow these instructions:

1. **Smoking.** Smoking can interfere with spirometry and MCT by producing false positive results. If you smoke cigarettes or other tobacco products, please abstain (don't smoke) for at least **6 hours prior** to your examination. If you are unable or unwilling to refrain from smoking during this time, please advise the physician of what time you last smoked. Please be advised that smoking on the day of the test may affect the diagnostic validity of your spirometry and/or MCT.
2. **Eating and Drinking.** You may eat a normal breakfast or lunch before your appointment, but do not eat heavily, drink any alcoholic beverage, or any particularly spicy foods (which may cause heartburn, indigestion, or reflux) on the day of your appointment. If possible, avoid coffee, tea, colas or other caffeinated beverages
3. **Exercise, Cold Air.** Do not participate in any strenuous exercise on the day of your evaluation. Please avoid any excess exposure to very cold or very hot air on the day of your appointment.
4. **Medications.** Certain asthma and other medications can also interfere with spirometry and/or MCT. The following table shows how long you should refrain from taking your medication before your appointment. You will be able to take your medication once the MCT has been completed. If you have any particular concerns about the safety of withholding any medication, please discuss it first with your treating physician.

Medication Class	Trade Names	Hours before appointment you should not use it
Short-acting inhaled bronchodilator	Albuterol Alupent Brethine Proventil Ventolin Xopenex	8
Long-acting inhaled bronchodilator	Foradil Serevent	48
Anticholinergic inhaler	Atrovent Spiriva	
Inhaled corticosteroids (etc.)	Advair Aerobid Flovent Azmacort Qvar Pulmicort Symbicort Vanceril	12
Theophylline	Theodur Theo-24	24
Atrovent nasal spray	Atrovent nasal spray	24
Antihistamine	Atarax Clarinex Claritin Zyrtec Over-the-counter cold or allergy products	48
Cromolyn inhaler	Intal	48
Leukotriene inhibitors	Accolate Singulair Zflo	48

Please review this page a few days before your appointment.

