Consent to participate in a research study

Cardiovascular and Respiratory Effects of Water Pipe Smoking

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Site where the study will be conducted: 1) American University of Beirut-Medical Center, Beirut Lebanon
                                         2) Hamad Medical Corporation Doha, Qatar

You are being asked to participate in a clinical research study conducted at the American University of Beirut and Hamad Medical Corporation. Please take time to read the following information carefully before you decide whether you want to take part in this study or not. Feel free to ask your doctor or the principal investigator if you need more information or clarification about what is stated in this form and the study as a whole.

You are being asked to participate in this study because you have either been smoking water pipe for more than 10 years or because you are non-smoker.

Since we do not know for sure if water pipe smoking is harmful to the heart, blood vessels and the lungs, we are conducting this study to find out whether water pipe smoking is associated with cardiovascular or respiratory impairment by comparing individuals who smoke water pipe with individuals who don’t smoke water pipe or cigarettes. We will ask 440 individuals to participate in this study, 220 in Beirut Lebanon and 220 in Doha Qatar. Participants will be approached directly in cafes, and by advertisement.

Participating means you will be asked to visit the American University of Beirut Medical Center where you will be interviewed by trained study personnel who will ask you questions about your health and smoking habits, measure and record your height, weight and blood pressure. Then you will be escorted by trained study personnel to the lab to undergo a vascular tonometry test, a breathing test (spirometry) and blood and urine tests, and then to the radiology department to undergo a chest CT for coronary artery calcium scoring. We will perform all those tests in one day if time permits.

Blood Pressure

Blood pressure will be measured by a trained study personnel while you are sitting using an inflatable cuff placed around your arm. You will be asked to rest and relax for 15 minutes before the first measurement. The cuff will be first inflated and will cause pressure feeling around your arm. The study personnel will use a stethoscope to listen to your pulse while deflating the cuff. The measurement will be repeated three times.

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Arterial Applanation Tonometry

Arterial applanation tonometry is a test that measures how stiff your blood vessels are. The stiffness of blood vessels gives an idea about vascular health and can show whether you’re at risk to develop hypertension or a heart attack or other heart problems before other signs and symptoms occur. The test is non-invasive which means that no surgery is done and no instruments are inserted into your body. You will be asked not to use stimulants such as caffeine, smoking or exercise for at least three hours before the test. During the test you will be asked to lie on your back on the examination table for 5-10 minutes and relax and you will be asked not to sleep. A trained study personnel or medical technician will locate your vascular pulse at the right neck area and at the right upper thigh near the groin by palpation. The distance between the two pulse sites will be measured using a measuring tape. Then, the tip of a tonometer, which is a metal object that looks like a pen, will be placed lightly against your skin over the vascular pulse sites at the neck and the upper thigh near the groin to obtain recordings of the pressure at the surface of your blood vessels. If you are a woman you can ask for a female staff to perform the test.

Spirometry

Spirometry is a test that measures how well your lungs work and can help diagnose various lung conditions. Spirometry shows how well you breathe in and out. Breathing in and out can be affected by lung diseases such as chronic obstructive pulmonary disease (COPD) and asthma. *Spirometry* is the name of the test and a spirometer is the device that is used to make the measurements. The spirometer has a mouthpiece that you use to blow into the device. First you breathe in fully and then seal your lips around the mouthpiece of the spirometer. You then blow out as fast and as far as you can until your lungs are completely empty. This can take several seconds. A clip may be put on to your nose to make sure that no air escapes from your nose. The measurements will be repeated three to six times to check that the readings are much the same each time you blow into the machine. Sometimes the tests are performed with you in a separate glass cubicle - this can help get more detailed and precise results. The mouth piece is single use and the machine is equipped with a bacteriological filter to prevent transmission of infectious disease.

Coronary Artery Calcium Scan

A coronary calcium scan is a test that looks for specks of calcium in the walls of the coronary (heart) arteries. These specks of calcium are called calcifications. Calcifications in the coronary arteries are an early sign of coronary heart disease. Coronary heart disease is the most common cause of heart attack. Because calcifications are an early sign of coronary heart disease, a coronary calcium scan can show whether you’re at risk for a heart attack or other heart problems before other signs and symptoms occur. A coronary calcium scan is a fairly simple test that takes about 10 minutes. You’ll be asked to lie quietly in the scanner machine. ECG leads will be applied over the skin of your chest and you will be asked to hold your breath for about 10 seconds while the machine takes pictures of your heart using X-rays. The pictures will show whether you have calcifications in your coronary arteries. A doctor will study the pictures to see whether you’re at risk for future heart attack. Coronary calcium scans have very few risks. The
test isn't invasive, which means that no surgery is done and no instruments are inserted into your body. Unlike some CT scans, coronary calcium scans don't require an injection of contrast dye to make your heart or arteries visible on x-ray images. The CT images will also include evaluation of your lungs for any abnormality. You will be notified for abnormality.

**Blood and Urine Tests**

Blood tests will include Cholesterol (LDL, HDL, Triglyceride), nicotine/cotinine level and several other tests that will tell us about the inflammation in your body like serum C-reactive protein (CRP) and interleukin-6 (IL-6), interleukin-18 (IL-18), Intracellular adhesion molecule (ICAM) and Fibrinogen. These tests could give an idea whether you're at risk for heart, lung or vascular problems before other signs and symptoms occur. Urine test will include micro albumin, nicotine/cotinine and isoprostane level a test that will tell us about the level of oxidative stress in your body.

**Risk**

Participation in the study is not expected to result in significant risk on your health. However there may be unforeseeable risk that we are unable to predict.

During this study, you will undergo one chest CT for coronary artery scoring; this radiological procedure might expose you to a dose up to 0.70mSv (70mrem), compared to 3 mSv (300mrem) we receive on a yearly basis from natural radiation sources that surround us. Although there are no proven harmful effects from radiation levels you will be exposed to during this study, long term effects on your health cannot be ruled out with certainty.

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You may not participate in this study if you are pregnant. If you are capable of becoming pregnant, a pregnancy test will be performed before you are exposed to any radiation. You must tell us if you may have become pregnant within the previous 14 days because the pregnancy test is unreliable during that time.

Participation in this study also requires collection of blood samples. Blood draws are usually associated with some discomfort from the needle prick and with possible side effects such as feeling lightheaded. There is also a small risk of bruising at the site of the needle prick and a very small risk of infection.

During blood pressure measurement a cuff will be inflated around your arm which will cause pressure feeling around your arm for few seconds which maybe uncomfortable to you.

During spirometry you will be asked to blow hard which may make you feel light headed, or may make you cough during the test.

**Benefits**

You will undergo several tests at no cost to you that will tell you about your risk of heart and blood vessels disease as well as any impairment in the function of your lungs.
If you are a patient at the American University of Beirut Medical Center and refuse to participate in this study, your relationship with your treating physician will not be affected, and you will never lose any of the benefits provided by the American University of Beirut Medical Center. Similarly if you are a patient at Hamad Medical Corporation and refuse to participate in this study, your relationship with your treating physician will not be affected, and you will never lose any of the benefits provided by the Hamad Medical Corporation.

If you agree to participate in this research study, the information will be kept confidential. Unless required by law, only the study doctor and designee, the ethics committee and inspectors from governmental agencies will have direct access to your medical records.

In case of any adverse event as a result of the study, there will be no compensation to cover such expenses in case it is not covered by a third party or governmental insurance.

If you agree to participate in this study we would like to contact you again in the future if we are doing more related studies.

Agreement to permit further contact in the future to participate in related studies (please check one)

☐ I permit further contact for participation in more studies.

☐ I do not permit further contact for participation in more studies.

Agreement for the use of questionnaire and medical record data (please check only one)

☐ I permit use of the questionnaire and hospital records data for further studies.

☐ I permit further contact to seek permission for the use of the questionnaire and hospital records data for further studies.

☐ I do not allow use of the questionnaire and hospital records data for further studies.

Investigator’s Statement:
I have reviewed, in detail, the informed consent document for this research study with __________________________ (name of patient, legal representative, or parent/guardian) the purpose of the study and its risks and benefits. I have answered to all the patient’s questions clearly. I will inform the participant in case of any changes to the research study.

Name of Investigator or designee __________________________ Signature __________________________

Date & Time __________________________

Patient’s Participation:
I have read and understood all aspects of the research study and all my questions have been answered. I voluntarily agree to be a part of this research study and I know that I can contact Protocol number IM.HC.03, Version 4, April 18 2013 Page 4 of 5

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APPROVED
Dr. Hassan Chami at (+961) 01 350000 pager 0443 or any of his/her designee involved in the study in case of any questions. If I feel that my questions have not been answered, I can contact the Institutional Review Board for human rights at (+961) 01 3500000 ext 5445. I understand that I am free to withdraw this consent and discontinue participation in this project at any time, even after signing this form, and it will not affect my care or benefits. I know that I will receive a copy of this signed informed consent.

Name of Patient or Legal Representative or Parent/Guardian

Signature

Date & Time

Witness’s Name
(if patient, representative or parent do not read)

Witness’s Signature

Date & Time