

MAY 06 2009

The US Environmental Protection Agency is seeking

ADULT VOLUNTEERS

Ages 50 to 75 for Research

**This is a research study about genetics,
diet supplementation and exposure
to air pollution.**

We are looking for healthy older adults to study diet
supplementation and the effects of air pollution
exposure on heart and lung function.

Total time commitment after screening is about 22 hours over 6 to
7 weeks. You will receive payment for screening, the study, and
out of town travel. Parking is provided.

1-888-279-9353 or
919-966-0604
www.epastudies.org



The Human Studies Facility is located on the UNC-CH campus

APR 27 2010

OMEGA CON STUDY
IRB # 07-0190 GCRC #2579

Purpose:

The main purpose of this research study is to determine if a component of ambient air pollution to which we are all exposed, particulate matter (PM), elevates the risks of cardiac changes and whether fish oil supplements will lessen the risks caused by PM. Results from this study may increase the understanding of how gaseous and particulate air pollutants (which causes the haze seen in some polluted cities) may adversely affect the functioning of the human cardiovascular and respiratory systems. This understanding may be especially important for patients with cardiopulmonary diseases.

Some of your blood will also be used to determine the type of a particular gene you carry. This gene, (GSTM1, glutathione-S-transferase) is one of several genes responsible for protecting your body against oxidants such as air pollutants, and some recent studies have shown that people carrying a mutation in this specific gene, which renders this gene inactive, may be more susceptible to the effects of air pollutants.

The current phase of this study is for healthy adults ages 50 to 75 who have the GSTM1 Null genotype. Volunteers initially undergo a blood test and genotype screening, for which you will be paid \$30. If after the initial genotyping visit you do not qualify for the study, your participation will end. If you do qualify for and complete the entire study, payment is incremental with a maximum total of \$1668.

Procedures:

If you qualify by genotype screening, you will have routine medical screening at the EPA Human Studies Facility, which includes completing medical history forms and a physical exam. You will be paid \$30 for the additional medical screening. If you are eligible for the study your participation will last approximately 6 to 7 weeks. Participation will require 6 weeks of dietary restrictions and four weeks of fish oil or olive oil treatment.

The study will begin with a training visit that will last about 3 hours and two exposure sessions which last about 8 hours each, with one 3-hour follow up session 18 hours after Exposure 2. Following training you will begin the treatment (taken as capsules) for 4 weeks prior to your exposure sessions. You will be asked to record your food intake twice for 3 days.

Procedures involved in this study include breathing tests, heart rate and blood pressure monitoring, including wearing overnight monitors after the exposure, blood draws, and ultrasound imaging of an artery in your arm. During the ultrasound procedure you will also be given a dose of nitroglycerine, which is a short-acting vasodilator. You will be exposed to a controlled amount of air pollution particles, no more than you might encounter if you visited a large city such as Los Angeles, New York, or Mexico City on a smoggy day. You will be asked to wear a heart rate monitor over night following exposure sessions.

The timing of this study is important: you must be able refrain from certain foods and medications for at least six weeks and to take the supplements for four weeks prior to the exposure. Does this sound like something that you would be interested in doing?

If yes, proceed to eligibility screening (IRB #95-0518, previously 95-EPA-66). Study specific inclusion/exclusion criteria appear in the IRB application (#GCRC 2579).

EX. 2

Recruitment Script

Study Restrictions:

In addition to the timing of the study, you must be willing to observe several important restrictions. They are:

- No use of over the counter pain medications such as aspirin, Advil, Aleve or other non-steroidal anti-inflammatory medications for 2 weeks prior to exposures. Low-dose aspirin and Tylenol (acetaminophen) are permitted.
- No intake of omega-3 fatty acids or having more than one 4-6 oz/serving of all types of fish and shellfish, walnuts, flaxseeds and flaxseed oil, rapeseed oil, canola oil, soybeans and soy products, Eggland's Best eggs, and cod liver oil for two weeks before and during the study.
- No intake of antioxidants (e.g., beta-carotene, selenium, vitamin C, vitamin E, zinc) for two weeks before and during the study.
- Must be willing to use olive oil for cooking, dressings, and sauces during the study.
- Must avoid drinking red wine during the study.
- Avoid smoke and fumes for 24 hours before all visits.
- Avoid drinking alcohol 24 hours before all visits.
- Avoid strenuous exercise for 24 hours prior to and after all visits.
- On the exposure day, you should eat a light breakfast.
- Must not eat pan fried and/or grilled foods after midnight prior to the exposure day.
- No caffeine for 12 hours prior to all study visits.
- Due to the overnight heart monitor must be willing to refrain from bathing between exposure and follow-up.

Would you be able to comply with these restrictions? If so, we can schedule you for an office visit to complete the initial part of the screening.

Study Schedule

Genotyping Visit, days/times TBD (less than 1 hour)

Medical History Screening, to be completed at home and mailed (1 hour)

Physical Exam: days and times TBD (2 hours)

Training (3 hours)

Dietary Supplementation (4 weeks)

Dietary Recordings, week 2 and week 4 (3 days/week)

Two Exposure Days (end of 4 weeks supplementation): 8:00 AM (8 hours each)

Follow-up Day: 18 hours after Exposure Day 2 (3 hours)

APR 27 2010

OMEGA CON STUDY (IRB #07-0190)
E-mail Announcement

SUBJECT: INFORMATIONAL: Research study for Healthy Older Adults

The main purpose of this research study is to determine if a component of air pollution, particulate matter (PM) elevates the risks of cardiac changes and whether fish oil supplements will lessen the risks caused by PM. Volunteers ages 50 to 75 will be tested to determine the type of a particular gene they carry, one of several genes responsible for protecting the body against oxidants. For this phase of the study only individuals with the GSTM1 Null genotype will be eligible. Participation will include four-weeks of fish oil or olive oil treatments and two exposures, to a controlled amount of PM. For more information, please visit our web site at www.epastudies.org or call Westat EPA Recruiting at 966-0604.

Approved [date] by the Office of Human Research Protection (OHRE) Biomedical Institutional Review Board. IRB # 07-0190 (GCRC #2579).

This email is sponsored by: U.S. Environmental Protection Agency Human Studies Division located on the UNC-Chapel Hill campus.

APR 27 2010

OMEGA CON STUDY
IRB # 07-0190 GCRC #2579

Purpose:

The main purpose of this research study is to determine if a component of ambient air pollution to which we are all exposed, particulate matter (PM), elevates the risks of cardiac changes and whether fish oil supplements will lessen the risks caused by PM. Results from this study may increase the understanding of how gaseous and particulate air pollutants (which causes the haze seen in some polluted cities) may adversely affect the functioning of the human cardiovascular and respiratory systems. This understanding may be especially important for patients with cardiopulmonary diseases.

Some of your blood will also be used to determine the type of a particular gene you carry. This gene, (GSTM1, glutathione-S-transferase) is one of several genes responsible for protecting your body against oxidants such as air pollutants, and some recent studies have shown that people carrying a mutation in this specific gene, which renders this gene inactive, may be more susceptible to the effects of air pollutants.

The current phase of this study is for healthy adults ages 50 to 75 who have the GSTM1 Null genotype. Volunteers initially undergo a blood test and genotype screening, for which you will be paid \$30. If after the initial genotyping visit you do not qualify for the study, your participation will end. If you do qualify for and complete the entire study, payment is incremental with a maximum total of \$1668.

Procedures:

If you qualify by genotype screening, you will have routine medical screening at the EPA Human Studies Facility, which includes completing medical history forms and a physical exam. You will be paid \$30 for the additional medical screening. If you are eligible for the study your participation will last approximately 6 to 7 weeks. Participation will require 6 weeks of dietary restrictions and four weeks of fish oil or olive oil treatment.

The study will begin with a training visit that will last about 3 hours and two exposure sessions which last about 8 hours each, with one 3-hour follow up session 18 hours after Exposure 2. Following training you will begin the treatment (taken as capsules) for 4 weeks prior to your exposure sessions. You will be asked to record your food intake twice for 3 days.

Procedures involved in this study include breathing tests, heart rate and blood pressure monitoring, including wearing overnight monitors after the exposure, blood draws, and ultrasound imaging of an artery in your arm. During the ultrasound procedure you will also be given a dose of nitroglycerine, which is a short-acting vasodilator. You will be exposed to a controlled amount of air pollution particles, no more than you might encounter if you visited a large city such as Los Angeles, New York, or Mexico City on a smoggy day. You will be asked to wear a heart rate monitor over night following exposure sessions.

The timing of this study is important: you must be able refrain from certain foods and medications for at least six weeks and to take the supplements for four weeks prior to the exposure. Does this sound like something that you would be interested in doing?

If yes, proceed to eligibility screening (IRB #95-0518, previously 95-EPA-66). Study specific inclusion/exclusion criteria appear in the IRB application (#GCRC 2579).

EX-2

Recruitment Script

Study Restrictions:

In addition to the timing of the study, you must be willing to observe several important restrictions. They are:

- No use of over the counter pain medications such as aspirin, Advil, Aleve or other non-steroidal anti-inflammatory medications for 2 weeks prior to exposures. Low-dose aspirin and Tylenol (acetaminophen) are permitted.
- No intake of omega-3 fatty acids or having more than one 4-6 oz/serving of all types of fish and shellfish, walnuts, flaxseeds and flaxseed oil, rapeseed oil, canola oil, soybeans and soy products, Eggland's Best eggs, and cod liver oil for two weeks before and during the study.
- No intake of antioxidants (e.g., beta-carotene, selenium, vitamin C, vitamin E, zinc) for two weeks before and during the study.
- Must be willing to use olive oil for cooking, dressings, and sauces during the study.
- Must avoid drinking red wine during the study.
- Avoid smoke and fumes for 24 hours before all visits.
- Avoid drinking alcohol 24 hours before all visits.
- Avoid strenuous exercise for 24 hours prior to and after all visits.
- On the exposure day, you should eat a light breakfast.
- Must not eat pan fried and/or grilled foods after midnight prior to the exposure day.
- No caffeine for 12 hours prior to all study visits.
- Due to the overnight heart monitor must be willing to refrain from bathing between exposure and follow-up.

Would you be able to comply with these restrictions? If so, we can schedule you for an office visit to complete the initial part of the screening.

Study Schedule

Genotyping Visit, days/times TBD (less than 1 hour)

Medical History Screening, to be completed at home and mailed (1 hour)

Physical Exam: days and times TBD (2 hours)

Training (3 hours)

Dietary Supplementation (4 weeks)

Dietary Recordings, week 2 and week 4 (3 days/week)

Two Exposure Days (end of 4 weeks supplementation): 8:00 AM (8 hours each)

Follow-up Day: 18 hours after Exposure Day 2 (3 hours)

APR 27 2010

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What is the purpose of this research study?

This study will find out if a component of ambient air pollution to which we are all exposed, particulate matter (PM) produced by gas and coal-fired power plants, increases the risks of changes in the heart and whether fish oil supplements will lessen the risks caused by PM. Researchers are studying the gene GSTM1, glutathione-S-transferase, that is one of several genes responsible for protecting your body against oxidants such as PM. Some recent studies have shown that people carrying a mutation in this specific gene, which renders this gene inactive, may be more susceptible to the effects of air pollutants. Results from this study will increase the understanding of how gaseous and particulate air pollutants (which cause the haze seen in some polluted cities) may adversely affect the functioning of the human cardiovascular and respiratory systems. This understanding may be especially important for patients with heart diseases.

Can I take part in the study?

You may be able to take part in the study if you are between the ages of 50 and 75.

What will I be asked to do?

- Have blood drawn to determine the type of GSTM1 gene you carry. Currently only those who are GSTM1 Null will be eligible.
- Eat a special diet for six weeks.
- Take fish oil or olive oil treatments for four weeks.
- Breathe clean filtered air and air with carefully controlled amounts of pollution particles.
- Take part in breathing tests, including one called spirometry (link provided to explanation).
- Have your heart rate monitored (link provided to explanation).
- Have a brachial artery ultrasound (BAU, link provided to explanation).
- Take a dose of nitroglycerine, a short-acting vasodilator.

How long will it take?

Following initial screening, the study will take between 15 and 22 hours over 6 or 7 weeks.

What will I get for volunteering?

If you complete all visits and procedures, we will pay you \$1668.

How can I sign up or get more information?

Call us or send an email. Our office hours are Monday-Friday from 8 am to 5 pm EST. After hours, please leave a message on voice mail, and we will return your call promptly.

- (919) 966-0604 (local)
- 1-888-279-9353 (toll free)
- recruitment@epa.gov

JUN 3 2009

OMEGA CON STUDY
IRB # 07-0190 GCRC #2579

Purpose:

The main purpose of this research study is to determine if a component of ambient air pollution to which we are all exposed, particulate matter (PM), elevates the risks of cardiac changes and whether fish oil supplements will lessen the risks caused by PM. Results from this study may increase the understanding of how gaseous and particulate air pollutants (which causes the haze seen in some polluted cities) may adversely affect the functioning of the human cardiovascular and respiratory systems. This understanding may be especially important for patients with cardiopulmonary diseases.

Some of your blood will also be used to determine the type of a particular gene you carry. This gene, (GSTM1, glutathione-S-transferase) is one of several genes responsible for protecting your body against oxidants such as air pollutants, and some recent studies have shown that people carrying a mutation in this specific gene, which renders this gene inactive, may be more susceptible to the effects of air pollutants.

This study is for healthy adults ages 50 to 75. Payment for the study is incremental with a maximum total of \$1668.

Procedures:

Volunteers initially undergo a blood test and genotype screening, followed by routine medical screening at the EPA Human Studies Facility, which includes completing medical history forms and a physical exam. You will be paid \$30 for the genotyping visit and \$30 for the additional medical screening. If you are eligible for the study your participation will last approximately 6 to 7 weeks. Participation will require 6 weeks of dietary restrictions and four weeks of fish oil or olive oil treatment.

The study will begin with a training visit that will last about 3 hours and two exposure sessions which last about 8 hours each, with one 3-hour follow up session 18 hours after Exposure 2. Following training you will begin the treatment (taken as capsules) for 4 weeks prior to your exposure sessions. You will be asked to record your food intake twice for 3 days.

Procedures involved in this study include breathing tests, heart rate and blood pressure monitoring, including wearing overnight monitors after the exposure, blood draws, and ultrasound imaging of an artery in your arm. During the ultrasound procedure you will also be given a dose of nitroglycerine, which is a short-acting vasodilator. You will be exposed to a controlled amount of air pollution particles, no more than you might encounter if you visited a large city such as Los Angeles, New York, or Mexico City on a smoggy day. You will be asked to wear a heart rate monitor over night following exposure sessions.

The timing of this study is important: you must be able refrain from certain foods and medications for at least six weeks and to take the supplements for four weeks prior to the exposure. Does this sound like something that you would be interested in doing?

If yes, proceed to eligibility screening (IRB #95-0518, previously 95-EPA-66). Study specific inclusion/exclusion criteria appear in the IRB application (#GCRC 2579).

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- No intake of omega-3 fatty acids or having more than one 4-6 oz/serving of all types of fish and shellfish, walnuts, flaxseeds and flaxseed oil, rapeseed oil, canola oil, soybeans and soy products, Eggland's Best eggs, and cod liver oil for two weeks before and during the study.
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Dietary Supplementation (4 weeks)

Dietary Recordings, week 2 and week 4 (3 days/week)

Two Exposure Days (end of 4 weeks supplementation): 8:00 AM (8 hours each)

Follow-up Day: 18 hours after Exposure Day 2 (3 hours)

JUN 2 2009

OMEGA CON: Elder Diet and Air Pollution Study

This is a study for healthy 50 to 75 year old adults. The main purpose of this research study is to determine if a component of ambient air pollution to which we are all exposed, particulate matter (PM), elevates the risks of cardiac changes and whether fish oil supplements will lessen the risks caused by PM. Results from this study may increase the understanding of how gaseous and particulate air pollutants (which causes the haze seen in some polluted cities) may adversely affect the functioning of the human cardiovascular and respiratory systems. This understanding may be especially important for patients with cardiopulmonary diseases. As a volunteer you will undergo a blood test to determine the type of a particular gene you carry. This gene, (GSTM1, glutathione-S-transferase) is one of several genes responsible for protecting your body against oxidants such as PM, and some recent studies have shown that people carrying a mutation in this specific gene, which renders this gene inactive, may be more susceptible to the effects of air pollutants.

Participation in this study will require six weeks of dietary restrictions and four weeks of fish oil or olive oil treatments, as well as one exposure to clean air and one to a controlled amount of air pollution particles, no more than you might encounter if you visited a large city such as Los Angeles, New York, or Mexico City on a smoggy day. Study procedures include breathing tests, heart rate and blood pressure monitoring, blood tests, and ultrasound imaging of an artery in your arm. During the ultrasound procedure you will also be given a dose of nitroglycerine, which is a short-acting vasodilator. Total time commitment after screening is about 22 hours, over 6-7 weeks. Compensation up to \$1668 is provided.

MAR 19 2009

OMEGA CON STUDY
IRB # 07-0190 GCRC #2579

Purpose:

The main purpose of this research study is to determine if a component of ambient air pollution to which we are all exposed, particulate matter (PM), elevates the risks of cardiac changes and whether fish oil supplements will lessen the risks caused by PM. Results from this study may increase the understanding of how gaseous and particulate air pollutants (which causes the haze seen in some polluted cities) may adversely affect the functioning of the human cardiovascular and respiratory systems. This understanding may be especially important for patients with cardiopulmonary diseases.

Some of your blood will also be used to determine the type of a particular gene you carry. This gene, (GSTM1, glutathione-S-transferase) is one of several genes responsible for protecting your body against oxidants such as air pollutants, and some recent studies have shown that people carrying a mutation in this specific gene, which renders this gene inactive, may be more susceptible to the effects of air pollutants.

This study is for healthy adults ages 50 to 75. Payment for the study is incremental with a maximum total of \$1418.

Procedures:

Volunteers initially undergo a blood test and genotype screening, followed by routine medical screening at the EPA Human Studies Facility, which includes completing medical history forms and a physical exam. You will be paid \$30 for the genotyping visit and \$30 for the additional medical screening. If you are eligible for the study your participation will last approximately 6 to 7 weeks. Participation will require 6 weeks of dietary restrictions and four weeks of fish oil or olive oil treatment.

The study will begin with a training visit that will last about 3 hours and two exposure sessions which last about 8 hours each, with one 3-hour follow up session 18 hours after Exposure 2. Following training you will begin the treatment (taken as capsules) for 4 weeks prior to your exposure sessions. You will be asked to record your food intake twice for 3 days each.

Procedures involved in this study include breathing tests, heart rate monitoring, including wearing overnight monitors after training and the exposure, blood draws, and ultrasound imaging of an artery in your arm. During the ultrasound procedure you will also be given a dose of nitroglycerine, which is a short-acting vasodilator. You will be exposed to a controlled amount of air pollution particles, no more than you might encounter if you visited a large city such as Los Angeles, New York, or Mexico City on a smoggy day. You will be asked to wear a heart rate monitor over night following exposure sessions.

The timing of this study is important: you must be able refrain from certain foods and medications for at least six weeks and to take the supplements for four weeks prior to the exposure. Does this sound like something that you would be interested in doing?

If yes, proceed to eligibility screening (IRB #95-0518, previously 95-EPA-66). Study specific inclusion/exclusion criteria appear in the IRB application (#GCRC 2579).

EX.2

MAR 19 2009

Study Restrictions:

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- No intake of omega-3 fatty acids or having more than one 4-6 oz/serving of all types of fish and shellfish, walnuts, flaxseeds and flaxseed oil, rapeseed oil, canola oil, soybeans and soy products, Eggland's Best eggs, and cod liver oil for two weeks before and during the study.
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Follow-up Day: 18 hours after Exposure Day 2 (3 hours)

OMEGA CON STUDY
E-mail Announcement

SUBJECT: INFORMATIONAL: Research study for Healthy Older Adults

The main purpose of this research study is to determine if a component of air pollution, particulate matter (PM) elevates the risks of cardiac changes and whether fish oil supplements will lessen the risks caused by PM. Volunteers ages 50 to 75 will be tested to determine the type of a particular gene they carry, one of several genes responsible for protecting the body against oxidants. Participation will include four-weeks of fish oil or olive oil treatments and two exposures, one to clean air and the other to a controlled amount of PM. For more information, please visit our web site at www.epastudies.org or call Westat EPA Recruiting at 966-0604.

Approved [date] by the Office of Human Research Protection (OHRE) Biomedical Institutional Review Board. IRB # 07-0190 (GCRC #2579).

This email is sponsored by: U.S. Environmental Protection Agency Human Studies Division located on the UNC-Chapel Hill campus.

APPROVED - IRB. UNC-CH
MAR 19 2009

EX.2

Web Site Advertising: www.epastudies.org

APPROVED - TPR, LINC-CH

MAR 19 2009

OMEGA CON: Elder Diet and Air Pollution Study

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EX. 2