

University of North Carolina - Chapel Hill

IRB Number: 07-0190 Legacy ID:
PI: Haiyan Tong IRB: Biomedical
Sponsor: EPA Intramural Federal Research
Study Title: GCRC-2579: Cardioprotective Effects of Omega-3 Fatty Acids Supplementation in Healthy Older Subjects Exposed to Air Pollution Particles

Certified: 06/22/2010

Reference ID: 1653

>> Brief Description of Event

A study subject (OMC-032) had cardiac arrhythmia (ventricular tachycardia) after clean air exposure. The brief arrhythmia was noted on a 24 hr Holter monitor recording and the subject had no symptoms

A1) Did this event occur at a site for which a UNC-CH IRB has direct oversight responsibility or involve a research participant at one of those sites? **Yes**

A2) Was the event unexpected in nature, severity, or frequency? **Yes**

Please explain:

We do not expect the study subjects have any cardiac arrhythmia after controlled clean air exposure. The 24 hr Holter monitor recording showed that the subject had a 4-beats ventricular tachycardia about 6 hrs after clean air exposure which is the control exposure. The subject had no symptoms and she was not doing any strenuous activities. The subject was consoled and was given a copy of the ECG. She was advised to see her own cardiologist for further investigation of her arrhythmia.

A3) Do you think the event was related or possibly related to this research? **No**

Based on your response this event is not required to be reported to the IRB. According to federal guidance and University policy, only events that are unexpected and related to the research must be reported. You may still have obligations to report this event to the research sponsor, coordinating center, data safety monitoring board (DSMB), or other oversight committee.

>> Attachments

There are no attachments for this event