**LBS 1 EMBARGOED Media Briefing 1:30-2:30 pm CT, Thursday, Nov. 12, 2020.**

[LBS 1 Briefing Speakers](https://newsroom.heart.org/_gallery/get_file/?file_id=5facb97a2cfac2160eb376f2&file_ext=.docx&page_id=)(doc)

DR. CHRISTINE ALBERT VITAL-Rhythm

TODAY I AM PRESENTING THE RESULTS OF THE VITAL RHYTHM OMEGA-3 FATTY ACID AND VITAMIN D SUPPLEMENTATION IN THE PRIMARY PREVENTION OF ATRIAL FIBRILLATION. I DO THIS ON BEHALF OF MY CO- OFFERS AT THE WOMEN'S HOSPITAL AND I AM AT SCENE OR SINAI HOSPITAL. THESE ARE THE DISCLOSURES. IMPORTANTLY, THIS CHILD WAS FUNDED , AND IT IS A SUBSTUDY OF ANOTHER TRIAL THAT WAS FUNDED BY THE NATIONAL CANCER INSTITUTE AND MULTIPLE NIH DIVISIONS. THE STUDY AGENTS WERE DONATED. THE RATIONALE FOR THIS TRIAL IS FIRST ATRIAL FIBRILLATION IS A COMMON AND GROWING HEART RHYTHM DISTURBANCE, ESTIMATED TO AFFECT 33 MILLION PEOPLE WORLDWIDE. IT RESULTS IN SIGNIFICANT SYMPTOMS AND IMPAIRS QUALITY OF LIFE. IT ALSO CONFERS RISKS OF A MULTITUDE OF MORBID FACTORS , SUCH AS STROKE AND HEART FAILURE AND EVEN DEATH. CURRENT TREATMENT OPTIONS ARE INTROIT RELATIVELY LATE IN THE DISEASE PROCESS, AFTER PEOPLE ALREADY PRESENT WITH ATRIAL FIBRILLATION. THEY ARE ASSOCIATED WITH SIGNIFICANT RISKS , AND LIMITED LONG-TERM SUCCESS RATES. SO, DESPITE THE PRESSING NEED FOR PRIMARY PREVENTIVE THERAPIES IN ATRIAL FIBRILLATION, THERE HAVE BEEN NO LARGE-SCALE STUDIES THAT I AM AWARE OF TESTING ANY OF THESE POTENTIAL STRATEGIES . LARGELY THIS IS THOUGHT TO BE DUE TO THE FACT THAT THEY WERE NOT FEASIBLE. THE BACKGROUND FOR TESTING THESE PARTICULAR AGENTS IS THAT PATIENTS OR PARTICIPANTS IN STUDIES WERE FOUND THAT HAD LOW LEVELS OF OMEGA-3 FATTY ACIDS AND VITAMIN D AND WERE FOUND TO HAVE HIGHER INCIDENCE OF ATRIAL FIBRILLATION, SUGGESTING THAT SUPPLEMENTATION MIGHT PREVENT ATRIAL FIBRILLATION, BUT THE DATA ARE SOMEWHAT CONFLICTING . THE VITAL RHYTHM TRIAL DESIGN WAS AN ANCILLARY STUDY OF VITAL RHYTHM. THAT WAS A PRIMARY PREVENTION TRIAL OF CARDIOVASCULAR DISEASE AND CANCER PERFORMED AMONG 25,871 MEN AND WOMEN IN THE UNITED STATES. IT IS A DOUBLE-BLIND PLACEBO- CONTROLLED RANDOMIZED TRIAL THAT TESTED DAILY SUPPLEMENTATION WITH 2000 IUS OF VITAMIN D , AND/OR, THE TWO BY TWO FACTORIAL DESIGN , 840 MILLIGRAMS OF OMEGA-3 FATTY ACIDS , COMPRISED OF 460 MILLIGRAMS OF EPA, AND 380 MILLIGRAMS OF DHA. THE CONCLUSION, MEN HAD TO BE AT LEAST 50 YEARS OF AGE, AND WOMEN WERE REQUIRED TO BE AT LEAST 55 YEARS OF AGE. THE PARTICIPANTS HAD TO HAVE NO HISTORY OF CARDIOVASCULAR DISEASE, CANCER, AND FOR VITAL RHYTHM, NO HISTORY OF ATRIAL FIBRILLATION. IT WAS CONFIRMED IN TWO WAYS. FIRST, PARTICIPANTS RECEIVED QUESTIONNAIRES, THIS WAS A MALE BASED STUDY WHERE THEY REPORTED THEIR HEALTH OUTCOMES, AND THEY REPORTED A NEW DIAGNOSIS ON FOLLOW-UP QUESTIONNAIRES. THEN IN ADDITION, WE LINKED THE COHORT TO THE DATABASE AND FOUND BILLING RECORDS AND HOSPITALIZATIONS FOR ATRIAL FIBRILLATION IN THESE PATIENTS. THEN WHEN WE IDENTIFY PATIENTS WHO MIGHT HAVE HAD A DIAGNOSIS BY EITHER OF THESE METHODS, WE WENT AHEAD AND GOT MEDICAL RECORDS TO CONFIRM THE EVENT, AND IT HAD TO BE CLEARLY CONFIRMED BY AN ECG OR MEDICAL RECORD REPORT . TO OUR KNOWLEDGE, THIS IS THE FIRST LARGE-SCALE LONG-TERM RANDOMIZED PLACEBO-CONTROLLED TRIAL TO TEST ANY INTERVENTION ON IT . SO, THE TRIAL POPULATION ENDED UP BEING 25,119 PARTICIPANTS WITH A MEAN AGE OF 67 AND 51% WOMEN AND 21% BLACK . THE INCIDENT OF AF EVENTS OVER 5.3 YEARS OF TREATMENT AND FOLLOW- UP, THERE WERE 900 EVENTS. 3.6% OF THE ENTIRE TRIAL POPULATION HAD A CONFIRMED AF EVENT. MOST OF THESE WERE CONFIRMED BY ECG, AND SOME WERE CONFIRMED BY MEDICAL RECORDS REPORTS. THIS SHOWS YOU THE BREAKDOWN OF PAROXYSMAL PERSISTENCE. THE MAJORITY WERE PROXIMAL THERE WERE A GOOD FRACTION THAT WERE PERSISTENT, AND THE MAJORITY HAD SYMPTOMS. THESE WERE CLINICALLY DIAGNOSED EVENTS, BUT THERE WAS A GOOD FRACTION THAT HAD NO SYMPTOMS PRIOR TO THEIR DIAGNOSIS. THIS STUDY HAD A 92% POWER TO DETECT A PREP 20% REDUCTION OR INCREASE IN THE OBSERVED HAZARD RATIO FOR INCIDENT . SO , THESE ARE THE STUDIES FOR THE RESULTS FOR THE EPA AND DHA ON INCIDENT AF INTENTION TO TREAT. THE FIRST LINE SHOWS THE INCIDENCE OF AF IN THE PLACEBO ARM , IN THIS PART OF THE TRIAL. THE SECOND LINE SHOWS THE EPA DHA. AS YOU CAN SEE, IT IS SLIGHTLY GREATER BUT NOT SIGNIFICANTLY SO. THE P IS 0.19 WITH A HAZARD RATIO OF 1.09, 95 PERCENT CONFIDENCE INTERVAL OF 0.962 1.24. FOR VITAMIN D , SIMILARLY , THIS IS THE PLACEBO ARM AND YOU CAN SEE , AGAIN, ABOUT A 3% HAZARD INCIDENCE OF ATRIAL FIBRILLATION , AND AGAIN, THE ACTIVE TREATMENT ARM WITH VITAMIN D3 DID NOT SHOW A REDUCTION OR AN INCREASE IN THE INCIDENCE OF ATRIAL FIBRILLATION. AGAIN , WITH A HAZARD RATIO OF 1.09, 95% CONFIDENCE INTERVALS OF 0.96 TO 1.25. SO , IN SUMMARY, SUPPLEMENTATION WITH OMEGA-3 FATTY ACIDS , 840 MILLIGRAMS, EPA DHA, AND OR 2000 IU PER DAY OF VITAMIN D3 DID NOT REDUCE OR INCREASE INCIDENT AF OVER MEDIAN TREATMENT DURATIONS OF 5.3 YEARS. OUR FINDINGS DO NOT SUPPORT THE USE OF EPA OR DHA OR VITAMIN D3 FOR PREVENTION OF INCIDENT AF. THEY ALSO DO NOT SHOW ANY INCREASE RISK IN ATRIAL FIBRILLATION FOR PATIENTS USING THESE SUPPLEMENTS FOR OTHER INDICATIONS. FUTURE RESEARCH TESTING OTHER STRATEGIES TO PREVENT AF IS NEEDED. THERE ARE SEVERAL OTHER STRATEGIES THAT INVOLVE LIFESTYLE, WEIGHT REDUCTION, BLOOD PRESSURE REDUCTION. I HOPE THIS TRIAL CAN PROVIDE A ROADMAP FOR HOW THESE TRIALS CAN BE PERFORMED. I THANK YOU FOR YOUR ATTENTION.