

ARIC Manuscript Proposal # 791

PC Reviewed: 04/04/01
SC Reviewed: _____

Status: A
Status: _____

Priority: N/A
Priority: _____

1.a. Full Title: Anti-cardiolipin antibodies (aCL) as a risk factor for venous thromboembolism (VTE) in a prospective study of healthy adults.

b. Abbreviated Title (Length 26 characters): aCL and VTE risk in LITE

2. Writing Group (list individual with lead responsibility first):

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Writing group members: Drs. A. Folsom, M Tsai, M. Cushman, P.McGovern

3. Timeline: March 2001 through June 2001

4. Rationale: This is part of the LITE (nested-case-control) ancillary study and serves as a MPH project.

While aCL have been shown to be a significant risk factor for VTE in case-control studies, primarily with underlying antiphospholipid antibody syndromes, this prospective study will address aCL as risk factor in healthy adults.

5. Main Hypothesis/Study Questions: There is a positive association between aCL and risk of venous thromboembolism in healthy adults. Study question 1: Independence of aCL as a risk factor for VTE. Study question 2: Linear trend of the association between aCL. Study question 3: Difference in risk association for IgG and IgM aCL.

6. Data (variables, time window, source, inclusions/exclusions):

Dependent variable: VTE case-control status (n = 335)

Covariates: Sex M,F
Age years, at diagnosis
Race
BMI
Factor VIII level
Factor V Leiden status

Independent variables: Level of IgG aCL
Level of IgM aCL

Source: Data from laboratory analysis of blood and cohort records of Longitudinal Investigation of Thromboembolism Etiology (LITE) study.

Exclusions: Baseline history of anticoagulant therapy

7.a. Will the data be used for non-CVD analysis in this manuscript? Yes No

b. If Yes, is the author aware that the file ICTDER02 must be used to exclude persons with a value RES_OTH = "CVD Research" for non-DNA analysis, and for DNA analysis RES_DNA = "CVD Research" would be used? Yes No

(This file ICTDER02 has been distributed to ARIC PIs, and contains the responses to consent updates related to stored sample use for research.)

8.a. Will the DNA data be used in this manuscript? Yes No

8.b. If yes, is the author aware that either DNA data distributed by the Coordinating Center must be used, or the file ICTDER02 must be used to exclude those with value RES_DNA = "No use/storage DNA"? Yes No

9. The lead author of this manuscript proposal has reviewed the list of existing ARIC Study manuscript proposals and has found no overlap between this proposal and previously approved manuscript proposals either published or still in active status. ARIC Investigators have access to the publications lists under the Study Members Area of the web site at: <http://bios.unc.edu/units/csc/ARIC/stdy/studymem.html>

Yes No