SAMPLE GRANT REVIEW

PRINCIPAL INVESTIGATOR: Dizzy, IM

TITLE OF GRANT: Role of Antidepressants in Dizziness in Older Persons with Depressive Symptoms

REVIEWER: John Smith, MD, PhD

SUMMARY OF PROJECT: Previous studies have demonstrated an association between dizziness and depressive symptoms, but the direction of the causal relationship remains unclear. The proposed project is a prospective cohort study of 100 older outpatients (from 2 geriatric assessments centers and one primary care clinic), designed to evaluate the frequency and severity of dizziness symptoms among older persons with depressive symptoms at baseline; then to follow these patients for four months to determine whether the addition of antidepressants in these patients leads to improvement or worsening of dizziness. The hypothesis is that adequate treatment of depressive symptoms may result in improvement in dizziness. Secondary aims are to evaluate whether antidepressants result in dizziness in depressed persons who do not have dizziness at baseline, and to identify risk factors associated with the onset of dizziness among older persons with depressive symptoms after antidepressant treatment. The patients will be enrolled by baseline interview in their homes, and followed up at 4 months. The primary outcome will be a change in the Dizziness Handicap Inventory Score between baseline and 4 months.

1. Overall Evaluation
   • Strengths
     o Overall, this is a strong proposal on a very interesting topic. The project poses substantial methodologic advances, particularly in the analysis phase. Definitely important work.

   • Weaknesses
     o More attention is needed towards description of the primary outcome measure, issues of potential confounding, and outlining of the specific analyses

2. Significance
   • Strengths
     o Nicely developed review of literature, addressing cogent areas, well balanced and no extraneous information provided.

   • Weaknesses
     o Would include a specific closing paragraph on the significance/importance of the proposed project, and how it will contribute to previous work in the field
3. Investigators
   • Strengths
     o The PI has an extensive record of research productivity, being a world renowned expert in dizziness.
     o Some members of the investigative team have worked together previously.
   • Weaknesses
     o None identified.

4. Innovation
   • Strengths
     o Challenge and seek to transform research on dizziness by utilizing novel theoretical concepts and approaches
   • Weaknesses
     o The investigators should call attention to the innovation of their project.

5. Approach
   • Strengths
     o In general the specific aims are clearly articulated, well-focused, and seem realistic.
   • Weaknesses
     o One suggestion is that a figure may be helpful to clarify the different study groups/subgroups and hypothesized directions of association to be tested—since it does become somewhat difficult to keep straight the various depressed/dizzy/treated groups.
     o A major question is whether it is important to distinguish between the various dizziness types (4 types identifiable through the dizziness questionnaire), as they may be etiologically distinct. In addition, antidepressants may be more or less beneficial in the different subgroups (e.g., useful for vertigo or abnormal head sensation; but perhaps may make presyncope worse)—perhaps a stratified analysis as a secondary aim may be helpful.
     o Data collectors: who are they? What is their training and standardization for this study? Is there blinding to study hypotheses?
     o Study instruments: more information on the validity and performance characteristics of the Dizziness Questionnaire, Dizziness numeric rating scale, and Dizziness Handicap Inventory should be provided.
     o Where will follow-up occur (home? Clinic? Phone?). Will postural vital signs be rechecked (seems that could worsen with antidepressant therapy)? Will intervening medical events be assessed, including other new medications which could lead to dizziness? How will patient’s who refuse or are lost to follow up be handled? Will any proxy data be collected?
Other study variables: Recommend including description of other important study variables, especially confounders, such as comorbidity, other medications which may lead to dizziness (diuretics, antihypertensives, sedative hypnotics, anticholinergics, etc.), orthostasis at baseline, etc.

6. Environment
   - **Strengths**
     - The institutional resources are excellent and more than adequate to carry out the proposed study, including data analytic support and resources.

   - **Weaknesses**
     - None noted.