



ChildrensHospitalLosAngeles

International Leader in Pediatrics

October 8, 2007

RESEARCH INFORMATION SHEET

Co-Enzyme Q10, L-Carnitine and Amitriptyline Usage in Cyclic Vomiting Syndrome (CVS): A Research Study

Dear CVS patient or parent of a CVS patient,

You are being asked to participate in a research study conducted by Richard G. Boles, M.D. from the Department of Medical Genetics at CHLA. We are conducting a research study in order to learn what the experiences are regarding two nutritional supplements, co-enzyme Q10 (also known as "Co-Q") and L-carnitine (Carnitor), and one medication, amitriptyline (Elavil), for the treatment of cyclic vomiting syndrome (CVS). We are conducting this research study primarily in order to determine what are the benefits and risks of these treatments, and in order to determine whether we should conduct a more detailed research study (a clinical trial).

An invitation to participate in this study is posted on the CVSA website at www.cvsaonline.org. In addition, you may have received this invitation because your name is on the Cyclic Vomiting Syndrome USA/Canada (CVSA) database, because you participated in a CVSA list on-line discussion, or because someone thought that you might be interested and sent this invitation to you (possibly from a CVSA patient, parent of a CVSA patient, CVSA member or volunteer, or a physician or other health care provider).

We are inviting you to participate in our study if you/your child have been diagnosed with cyclic vomiting/CVS by a physician or other health care provider (nurse practitioner, etc.).

If you/your child were **never** treated with co-enzyme Q10, L-carnitine or amitriptyline, please put an "X" in the box to the left and return only this page to us. We are asking you to do this because we would like to know what proportion of CVS patients have tried one of these treatments, and we cannot know this if we do not know how many patients have not tried one of these treatments.

If you/your child were treated with co-enzyme Q10, L-carnitine and/or amitriptyline, we are asking that you complete a questionnaire for each of the treatments that were tried, and the General Questionnaire. In order to obtain more complete and accurate data, we would like to hear from you regardless of what your experience was. Thus, if one or both of these treatments helped you/your child, if they did nothing, or if you stopped them because of side effects, we would like to hear about your experience. We also would like to hear from you regardless of your/your child's age, from birth through senior citizens. However, the choice of whether or not you to participate is entirely yours.

Since this invitation is being sent to thousands of families, and as we are not asking you for your name or contact information, we will not know if you participated or not. Thus, you may receive another invitation whether or not you complete and return the questionnaires. Please only complete the questionnaire once per affected person, even if you receive both paper and electronic copies.

There are no direct risks or benefits to you from participating. However, your participation may help us to best advise CVS patients and families in general regarding treatment options.

If you/your child have been diagnosed with CVS, tried one or more of the following treatments, and you decide to participate, we ask that you complete the following questionnaires:

1. The "General Questionnaire": This will help us to understand which characteristics of CVS patients are associated with both beneficial and harmful effects of these treatments.
2. The "Co-Enzyme Q10 Questionnaire": Please complete if you/your child has ever taken co-enzyme Q10. Otherwise, simply mark the "No" answer in the first question and leave the rest blank.
3. The "L-Carnitine Questionnaire": Please complete if you/your child has ever taken L-carnitine. Otherwise, simply mark the "No" answer in the first question and leave the rest blank.

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4. The "Amitriptyline Questionnaire": Please complete if you/your child has ever taken amitriptyline. Otherwise, simply mark the "No" answer in the first question and leave the rest blank.

The paper and electronic copies of the questionnaire are identical. Note: it is possible that the answers you provide could make you ineligible for participation. If this is the case, your data will not be included in the study.

If you received paper copies, you can complete them in pen, and then mail, fax or e-mail (a scanned version) the completed questionnaires to Amy Preston (contact information below). We have provided an addressed return envelope, but we are requesting that you use your own stamps. However, you can also go to the cvs a website at www.cvs aonline.org to get a Word file of the questionnaires, which can be completed on the computer and e-mailed to Amy.

If you received electronic copies (all are contained in a single Microsoft Word file), you can complete them on your computer and return them to Amy by e-mail. You can also print the questionnaires, complete them in pen, and return them to Amy by postal mail or fax.

Your answers are completely confidential. Amy will remove and discard any personal identifying information, including any postmark, fax heading or electronic signature, before forwarding the information to the other investigators including Dr. Boles.

If more than one member of your family took co-enzyme Q10, L-carnitine and/or amitriptyline, either for the treatment of CVS, migraine headaches or muscle cramps, we ask that each relative complete separate questionnaires for each. You can photocopy the blank questionnaires for this purpose. Participating individuals who do have migraine or muscle cramps, but not CVS, do not need to complete the General Questionnaire.

We intend to publish any findings that would be of interest to CVS sufferers and families in *Code V*, the official newsletter of the CVSA, and on the CVSA website at www.cvs aonline.org once the study is completed, fully evaluated, and (likely) published in a medical/scientific journal. Some basic information regarding the co-enzyme Q10 and L-carnitine supplements was published recently in the Spring 2006 edition of *Code V*, as well as on the CVSA website.

Thank you for your consideration,

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Please return completed questionnaires by mail, fax or e-mail to Amy Preston at:

Address: CVSA Research Study
P.O. Box 4164
Clifton Park, New York 12065
Fax 414-342-8980
E-mail apreston-cvs a@nycap.rr.com

If you have any questions about the study, please contact Amy as listed above.

RIGHTS OF RESEARCH SUBJECTS

You may withdraw your permission for your/your child's participation at any time and discontinue participation without penalty. You are not waiving any legal claims, rights or remedies because of your/your child's participation in this research study. If you have questions regarding your/your child's rights as a research subject, you may contact the CHLA Office for Human Subjects Protections at 323/669-2265.