

Collaborative Antiviral Study Group



eBrief
Summer 2015



SPOTLIGHT ON ROCHESTER!

The research group in the Pediatric Infectious Disease Unit at the University of Rochester Medical Center, in Rochester, New York focuses on conducting translational research studies of viral infections in children. We are a proud member of the CASG and also participate in other studies through DMID, the NIH, and industry sponsors. Our group interacts with people from all over our large, university-affiliated hospital who come together to assist in these important endeavors.

Mary Caserta, MD, Professor, is the Principal Investigator for the CASG projects.

Gerry Lofthus, PHD, CCRC, Senior Instructor, is the Study Coordinator for the CASG projects.

Amy Murphy, RN, BSN, is our research nurse who works on all studies for our team.

Our lab group consists of **Ken Schnabel, Jennifer Carnahan, Lisa Denmark** and **Lynne Shelley**. Each of them does an amazing job of working with the clinical microbiology lab to obtain remnant blood samples for the GeneXpert study, processing, freezing and preparing samples for shipment for our CASG studies.

Working on the HSV GeneXpert study has allowed us to work more closely with our colleagues in Obstetrics. The nurses working on the Birth Center units and in high risk obstetrics have risen to the challenge of this busy study. We collaborate with three OB nurses on two different units. These women have completed all the necessary training to obtain consent and contribute impressive numbers of subjects to the study. Jan Demarco, Deb Good, and Sharon Bolaji-Thomas have been an incredible extension of our group. Thanks also to all the other nurses who help us each and every day in approaching their patients and securing our samples.



Deb Good, enrolling Nurse on the Birth Center



Gerry Loftus, Mary Caserta, Ann Murphy



Jan Demarco, enrolling Nurse on the Birth Center



Our Lab Staff:

Top L – Lisa Denmark
 Top R – Ken Schnabel
 Bottom L – Jennifer Carnahan
 Bottom R – Lynne Shelley



Sharon Bolaji-Thomas, enrolling Nurse on the Birth Center



Happy retirement to Sharon Blount!!

As you all may know, after more than 29 years of hard work for the CASG in the Virology Lab, Sharon Blount is retiring.

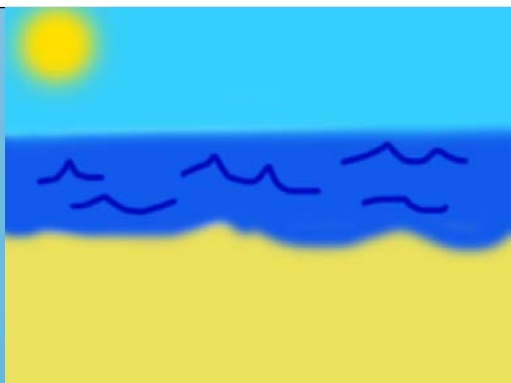
We know many of you have probably worked closely with Sharon over the years. If you would like to send her a congratulatory email please send to pjester@peds.uab.edu; we will print them and give to her. She has been a strong contributor to the CASG...without our virology lab, we would be lost!

So as of June 1, 2015, Sharon Blount, our long time Lab Manager, is retired. Going forward, your new CASG-CU Lab Contact will be **Jennifer Potter**. Jennifer is not new to our lab, but she is new to this position. Jennifer can be contacted at jpotter@peds.uab.edu. (You will begin to see her name, and will receive emails from Jennifer.)

Letter from the Lab!!

In order to help Jennifer Potter transition smoothly to the Lab Manager position, we are requesting that all emails requesting supplies contain the following information:

- *Your name
- *Your site's name
- *Your site number
- *The protocol name/number for which you are requesting supplies



GAN PREMIE, 11-0067 GROUP CLOSURE NOTICE!!

As you may recall, our sample size targets are to enroll 8 subjects in each of the following four groups:

Group 1: ≤ 27 weeks 6 days gestational age at birth and ≤ 30 days chronologic age at study enrollment OPEN

Group 2: ≤ 27 weeks 6 days gestational age at birth and > 30 days chronologic age at study enrollment CLOSED 18 March 2015

Group 3: ≥ 28 weeks 0 days gestational age at birth and ≤ 30 days chronologic age at study enrollment OPEN

Group 4: ≥ 28 weeks 0 days gestational age at birth and > 30 days chronologic age at study enrollment OPEN

Eight of the 10 subjects enrolled to date have been in Group 2, so we are closing that group to further enrollment. The remaining three groups remain open, and we greatly appreciate your renewed focus on finding patients who could enroll in the three OPEN groups.

Please let us know if you have any concerns or if this is not clear. Because the eDES will not prevent enrollment of subjects in the closed age group, please be careful to enroll subjects whose age falls in the parameters defined for Group 1, 3 or 4.



MEETING MINUTES AND ATTENDANCE LOGS

Please be sure to print a copy of the minutes from your monthly or bi-monthly phone call with CASG, as well as a copy of the attendance log. Both the minutes and the attendance log are emailed to you following the meeting. These copies must be kept in the Training section of your Project Notebook. A monitor will be looking for these during your Monitor Visit!

MONTHLY PHONE MEETING SCHEDULE

We have been very pleased with the participation in the regular (monthly and bimonthly) calls that we have scheduled for each of the five protocols. Just as a quick review:

BK study (11-0071) – irregular call schedule

Valgan Toddler study (11-0069) – 2nd Thursday each month

CMX001 study (11-0068) – 2nd Thursday each month

GeneXpert study (11-0070) – 3rd Thursday every other month (June, August, etc.)

Gan Premie study (11-0067) – 3rd Thursday every other month (June, August, etc.)



REMINDER: Failed Screening Monthly Data

Not all potential patients are eligible to be research subjects or want to be a research subject. These individuals are grouped as **failed screening** patients. This is important information for researchers to capture during the implementation of a clinical trial because the data can identify decline trends in recruitment and enrollment efforts. Strategies may be developed to help research teams meet these challenges. Please remember to enter your failed screening data on the failed screening webpage located on the Central Unit (CASG) password protected webpage. The data is reviewed monthly by the data management group and reports are submitted to the Central Unit.



We are pleased to report that after many years of work, the results of the CASG 112 study were published **in the NEJM on March 5, 2015. The current CMV Valgan Toddler study, DMID 11-0069, that many sites are now activating, follows up on** the data from this earlier study and will, hopefully, expand on our knowledge of treatment of CMV in children. Thank you to all participating CASG 112 sites for your contributions to this major publication. We have included the abstract here.

ORIGINAL ARTICLE

Valganciclovir for Symptomatic Congenital Cytomegalovirus Disease

D.W. Kimberlin, P.M. Jester, P.J. Sánchez, A. Ahmed, R. Arav-Boger, M.G. Michaels, N. Ashouri, J.A. Englund, B. Estrada, R.F. Jacobs, J.R. Romero, S.K. Sood, M.S. Whitworth, M.J. Abzug, M.T. Caserta, S. Fowler, J. Lujan-Zilbermann, G.A. Storch, R.L. DeBiasi, J.-Y. Han, A. Palmer, L.B. Weiner, J.A. Bocchini, P.H. Dennehy, A. Finn, P.D. Griffiths, S. Luck, K. Gutierrez, N. Halasa, J. Homans, A.L. Shane, M. Sharland, K. Simonsen, J.A. Vanchiere, C.R. Woods, D.L. Sabo, I. Aban, H. Kuo, S.H. James, M.N. Prichard, J. Griffin, D. Giles, E.P. Acosta, and R.J. Whitley, for the National Institute of Allergy and Infectious Diseases Collaborative Antiviral Study Group

ABSTRACT

BACKGROUND

The treatment of symptomatic congenital cytomegalovirus (CMV) disease with intravenous ganciclovir for 6 weeks has been shown to improve audiologic outcomes at 6 months, but the benefits wane over time.

METHODS

We conducted a randomized, placebo-controlled trial of valganciclovir therapy in neonates with symptomatic congenital CMV disease, comparing 6 months of therapy with 6 weeks of therapy. The primary end point was the change in hearing in the better ear (“best-ear” hearing) from baseline to 6 months. Secondary end points included the change in hearing from baseline to follow-up at 12 and 24 months and neurodevelopmental outcomes, with each end point adjusted for central nervous system involvement at baseline.

RESULTS

A total of 96 neonates underwent randomization, of whom 86 had follow-up data at 6 months that could be evaluated. Best-ear hearing at 6 months was similar in the 6-month group and the 6-week group (2 and 3 participants, respectively, had improvement; 36 and 37 had no change; and 5 and 3 had worsening; $P=0.41$). Total-ear hearing (hearing in one or both ears that could be evaluated) was more likely to be improved or to remain normal at 12 months in the 6-month group than in the 6-week group (73% vs. 57%, $P=0.01$). The benefit in total-ear hearing was maintained at 24 months (77% vs. 64%, $P=0.04$). At 24 months, the 6-month group, as compared with the 6-week group, had better neurodevelopmental scores on the Bayley Scales of Infant and Toddler Development, third edition, on the language-composite component ($P=0.004$) and on the receptive-communication scale ($P=0.003$). Grade 3 or 4 neutropenia occurred in 19% of the participants during the first 6 weeks. During the next 4.5 months of the study, grade 3 or 4 neutropenia occurred in 21% of the participants in the 6-month group and in 27% of those in the 6-week group ($P=0.64$).

CONCLUSIONS

Treating symptomatic congenital CMV disease with valganciclovir for 6 months, as compared with 6 weeks, did not improve hearing in the short term but appeared to improve hearing and developmental outcomes modestly in the longer term. (Funded by the National Institute of Allergy and Infectious Diseases; ClinicalTrials.gov number, NCT00466817.)

The authors' full names, degrees, and affiliations are listed in the Appendix. Address reprint requests to Dr. Kimberlin at the Division of Pediatric Infectious Diseases, University of Alabama at Birmingham, 1600 Seventh Ave. S., Children's Harbor Bldg., Rm. 303, Birmingham, AL 35233, or at dkimberlin@peds.uab.edu.

N Engl J Med 2015;372:933-43.

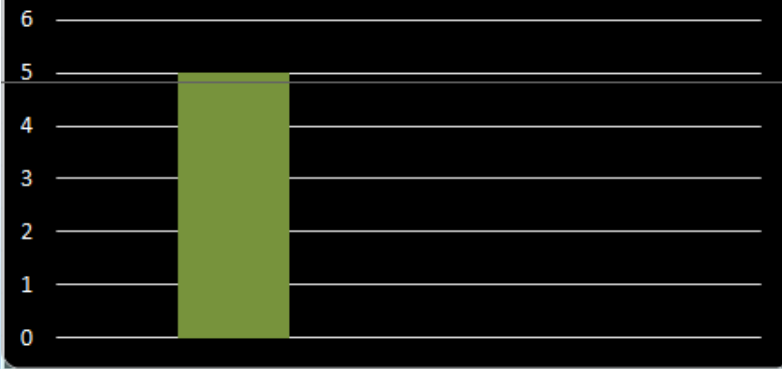
DOI: 10.1056/NEJMoa1404599

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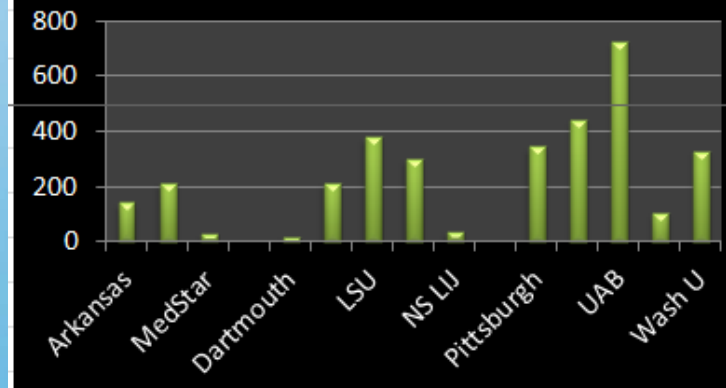
Enrollment Update!

GeneXpert

Group 1 Enrollment - UAB

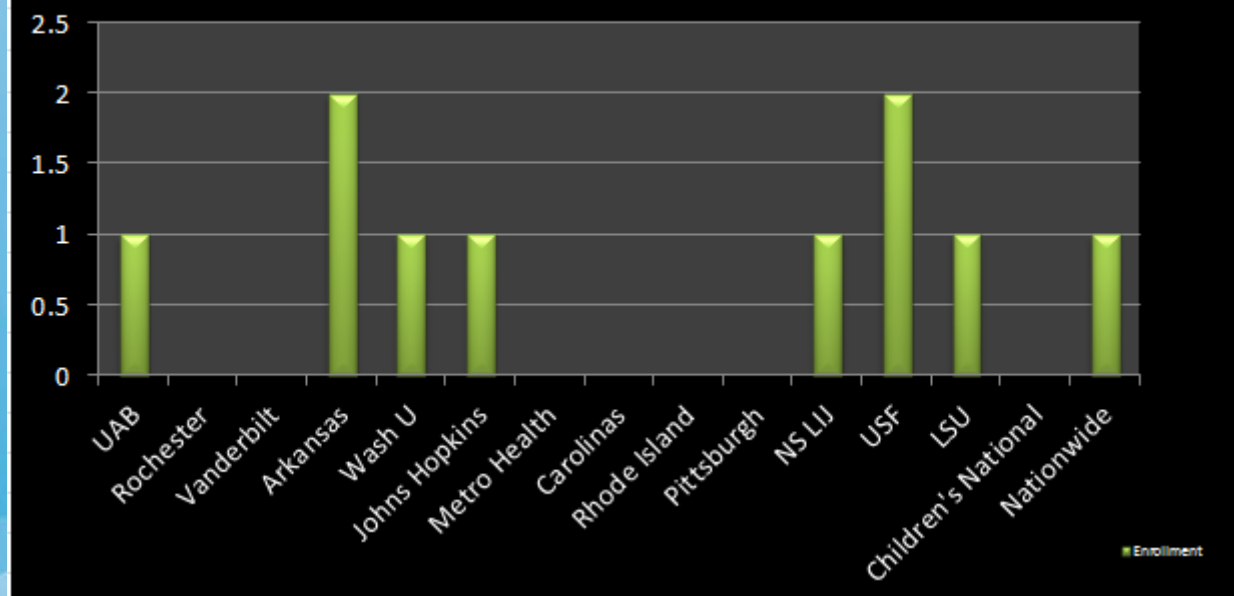


Group 2 Enrollment



Gan Premie

Enrollment



Enrollment Update Continued!

BK Virus

