

METASTATIC OOPHORECTOMY AND TAMOXIFEN STUDY NEWS

April 2009

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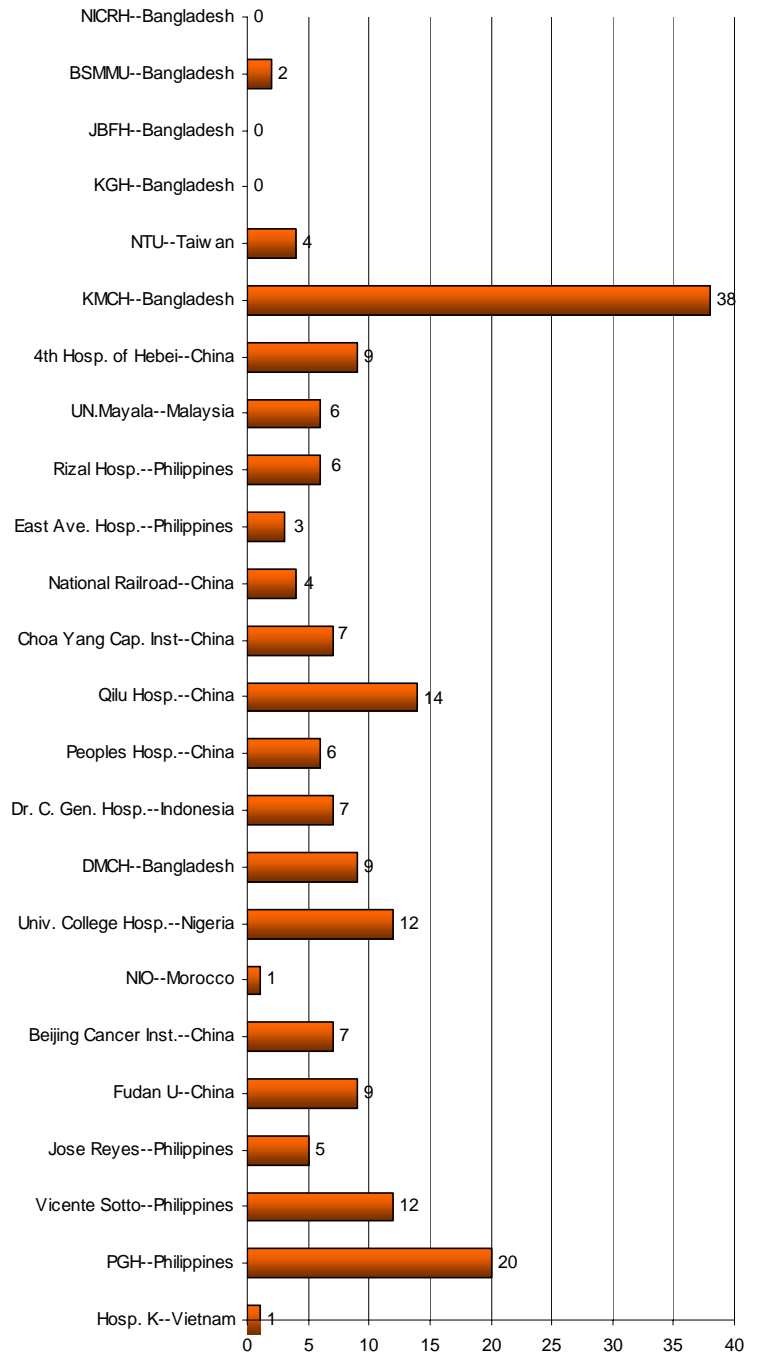
OVER HALF OF ENROLLMENT COMPLETED!

As of April 30, 2009, **182 patients** have been entered into the study, which is over half of the 350 targeted for enrollment! Congratulations to all study site participants for reaching this milestone!

Recently, a new site, **Khaosing Veterans General Hospital** in Kahosing, Taiwan, was approved to begin entering patients on study. We are pleased to have their participation and look forward to increased study enrollment as a result.

BSMMU hospital in Bangladesh is the latest new contributor of patients to the study. We are excited to have a new actively enrolling site!

Study participation has been steady in the past few months, with contributions from both new and old sites. Your continued efforts to identify and enroll new patients is very much appreciated!



Partners in Research:



LABORATORY MODELS SUPPORT STUDY RATIONALE

There are increasingly frequent reports of laboratory studies showing that the stress of surgeries promotes tumor growth through promotion of angiogenesis. Such reports support our thinking about angiogenesis mechanisms through which luteal phase surgical oophorectomy may confer greater benefit to patient with metastatic breast cancer. Specifically, in the Journal Clinical Cancer Research April 15, 2009 (Surgical stress promotes tumor growth in ovarian carcinoma, Lee, J-W. et al 2009;15:2695-2702) investigators show with two ovarian cancer cell lines injected intraperitoneally in nude mice, that surgical stress with mastectomy or laparotomy increased tumor nodule weight and numbers, and microvascular

density and VEGF expression. Fascinatingly also, administration of a B blocker propranolol, blocked these effects of surgical stress.

Such reports support our thinking about angiogenesis mechanisms through which luteal phase surgical oophorectomy may confer greater benefit to patient with metastatic breast cancer. These reports make our study even more important and exciting.

NEW STUDY STAFF



Dorsia Wakawa is our new Research Manager. Her degree is in health information management and she has experience in various aspects of clinical research including developing software for managing patient data and coordinating clinical research studies.



Lesla Smith is our new Administrative Assistant. She has replaced Karen Feasel.

STUDY FACTS

- There are currently 20 participating sites that have accrued one or more patients since the study began
- Nine countries participate in this trial
- Three countries have accrued over 40 patients each (the Philippines, China, and Bangladesh)
- We have reached 52% of our accrual goal to date.

ANNUAL IRB REVIEW TIME

It's that time of year again—Ohio State University requires that all participating research sites provide a renewal letter for the metastatic study. A letter must be submitted showing IRB approval of the study from each institute. Additionally, we must show that each site continues to be approved by the U.S. Office of Human Research Protection (OHRP). All sites are currently approved, but please be sure to monitor when your approval expires to ensure the study can continue without interruption.

Why this process? By ensuring an annual review of this project by all sites we take the time to reflect on the value of this study for our participants. We ask questions such as whether this continues to be the most appropriate treatment for our eligible patients or whether some new treatment has been discovered that may be better for our patients. Currently we feel this continues to be the best available treatment (used worldwide) for our eligible patients, but this time next year we will be asking your IRB to conduct a new review.

BREAST CANCER ENTERTAINMENT EDUCATION

Promoting breast cancer awareness and encouraging women to seek care for breast problems can be fun and entertaining. A theater group in Bangladesh, “Rupantar” has been working with a researcher at Arizona State University to develop and evaluate a 15 minute performance incorporating traditional dance, music, and artwork about breast cancer. The performance is designed to be conducted in villages where it reaches entire families and those who may be illiterate or not have access to other forms of media (i.e., television). In June of this year and throughout the summer an evaluation of this performance will be conducted with 20 villages in the Khulna Division of Bangladesh .



Pilot breast cancer awareness program by Rupantar



Examples of artwork used in the performance

HOSPITAL DISCHARGE FORM AND FOLLOW UP FORM

There has been some confusion about how to fill out the Hospital Discharge/FU 1/FU2/FU 3 Form and how this form relates to the Measurement form. Here are some guidelines (slightly different than an earlier version we sent out) which should help clarify.

Hospital Discharge/FU 1/FU 2/FU 3 Form

This form is completed at the following time points:

- within 2 weeks of surgery (Hospital Discharge box checked)**
- 1 month after surgery (FU 1 box checked)**
- 2 months after surgery (FU 2 box checked) PLUS Measurement Form**
- 3 months after surgery (FU 3 box checked) PLUS Measurement Form**

THE MEASUREMENT FORM IS FILLED OUT AT THE FU 2 and FU 3 TIME PERIOD AND THEN WITH EVERY FOLLOW UP (THE “FOLLOW-UP” FORM).

Follow-up Form

This form is completed at the following time points:

Month 5, 7, 9...etc. Every two months after the first three months.

The Measurement Form is also filled out at this time.

Other Notes:

- As soon as a progression is found the Disease Progression Form is filled out
- As soon as an adverse event is found, an Adverse Event Form is filled out AND the Study Coordinators/PI are contacted.
- When a patient dies the Death Form AND the Adverse Event Form are filled out.

CONTACT US

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Check out the www.ibcrf.org website!

We would appreciate any news, patient success stories, pictures or suggestions for our next newsletter.

Please e-mail Heather.Roberto@osumc.edu

*R E S E A R C H . . . F I N D I N G A N S W E R S F O R W O M E N
E V E R Y W H E R E*

ACTIVE STUDY SITES AS OF APRIL 2009 (NEW IN BLUE)**Bangladesh**

- Dhaka Medical College and Hospital, Dhaka
- BangaBandhu Shiekh Mujib Medical University, Dhaka
- Japan Bangladesh Friendship Hospital, Dhaka
- Khulna Medical College Hospital, Khulna
- Kushtia General Hospital, Kushtia

Vietnam

- Hospital K, Hanoi

Morocco

- National Cancer Institute (INO), Rabat

Nigeria

- University College Hospital, Ibadan

Indonesia

- Dr. Ciptomanouksumo General Hospital, Jakarta

China

- Cancer Institute, Beijing
- People's Hospital, Beijing
- Chao Yang Capital Institute, Beijing
- National Railway, Beijing
- Beijing Hospital, Beijing
- Qilu Hospital Consortium, Jinan
- Fudan University Cancer Center, Shanghai
- Fourth Hospital of Hebei Medical University, Hebei

Malaysia

- University of Malaya Medical Center, Kuala Lumpur

Philippines

- Philippines General Hospital, Manila
- East Avenue Medical Center, Manila
- Vicente Sotto Memorial Medical Center, Cebu
- Rizal Memorial Medical Center, Manila
- Santo Tomas Hospital, Manila

Taiwan

- National Taiwan University Hospital
- [Kaohsiung Veterans General Hospital](#)