Prediction of ovarian cancer using a multivariate assay: a randomized controlled trial to improve diagnostic strategies in Filipino women

SECONDARY IDENTIFICATION NUMBER

N/A

FDA CLINICAL TRIAL REFERENCE (CTR) NUMBER

N/A

SCIENTIFIC TITLE

Prediction of ovarian cancer using a multivariate assay: a randomized controlled trial to improve diagnostic strategies in Filipino women

PROJECT DESCRIPTION

This study will evaluate a multiplex biochemical assay (OVERA) for malignancy risk calculation within a tertiary hospital management algorithm for ovarian cancer. It shall provide further understanding of the biochemical profile of adnexal masses and their concomitant ultrasound and histopathologic features to ultimately assess their utility in our local setting.

NUHRA DETAILS

<table>
<thead>
<tr>
<th>Regime</th>
<th>Classification</th>
<th>Priority</th>
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<td>2017 - 2022</td>
<td>Responsive health systems</td>
<td>Diagnostics</td>
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PROJECT DURATION

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<th>Duration in Months</th>
<th>Target Completion Date</th>
<th>Actual Completion Date</th>
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<td>2017-10-02</td>
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<td>2021-04-02</td>
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PROJECT STATUS

Ongoing

REASON FOR PROJECT PENDING/SUSPENSION/TERMINATION

Unspecified

IMPLEMENTING AGENCY (PRIMARY SPONSOR)

<table>
<thead>
<tr>
<th>Institution</th>
<th>Classification</th>
<th>Region</th>
<th>LTO #</th>
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<tbody>
<tr>
<td>University of the Philippines - Manila, College of Medicine, Department of Physiology</td>
<td>Public Higher Education Institution - State Universities and Colleges</td>
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COORDINATING AGENCY (SECONDARY SPONSOR)

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</table>

CONTACT RESEARCH ORGANIZATION (CRO) INFORMATION

Contact #: (+632) 8377534, (+632) 8377537, (+632) 8372071-80 loc. 2117, 2112
Saliksik Building, DOST Compound, Gen. Santos Ave., Bicutan Taguig City 1631 Philippines

Page 1/5
Institution | Classification | Region | LTO # |
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No records Found. |

**FUNDING AGENCY (SOURCES OF MONETARY OR MATERIAL SUPPORT)**

<table>
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<tr>
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**CONTACT FOR PUBLIC QUERIES**

<table>
<thead>
<tr>
<th>Name</th>
<th>E-Mail</th>
<th>Phone Number</th>
<th>Institution and Institution Address</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clarissa L. Velayo, MD, PhD</td>
<td><a href="mailto:clvelayo@up.edu.ph">clvelayo@up.edu.ph</a></td>
<td>09171542040</td>
<td>Department of Physiology, College of Medicine, University of the Philippines, 547 Pedro Gil Street corner A. Mabini, Ermita, Manila 1000 Philippines</td>
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**IMPLEMENTING AGENCY (PRIMARY SPONSOR)**

<table>
<thead>
<tr>
<th>Name</th>
<th>Expertise</th>
<th>Affiliation</th>
</tr>
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<tbody>
<tr>
<td>Clarissa Lim Velayo, MD, PhD</td>
<td>Developmental Physiology, Obstetrics and gynecology; Maternal and Fetal Medicine</td>
<td>University of the Philippines - Manila, College of Medicine, Department of Physiology</td>
</tr>
<tr>
<td>Kareen N. Reforma, MD</td>
<td>Obstetric and Gynecologic Ultrasound</td>
<td>University of the Philippines - Philippine General Hospital</td>
</tr>
<tr>
<td>Michele H. Diwa, MD</td>
<td>Pathology</td>
<td>University of the Philippines - Philippine General Hospital</td>
</tr>
<tr>
<td>Renee Vina G. Sicam, MD</td>
<td>Gynecologic Oncology</td>
<td>University of the Philippines - Philippine General Hospital</td>
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**RESEARCH CLASSIFICATION**

Clinical Trial

**HEALTH CONDITION(S) OR PROBLEM(S) STUDIED**

For women with ovarian cancer, outcome is highly dependent on the proper timing and institution of care with referrals to a gynecologic oncologist to perform specific surgical procedures as a key determinant to ascertain stage and future treatment measures. An inadequate surgery will equate to delayed or worse, to erroneus treatment, which either way is detrimental to patient survival. Inadequate surgery is still a problem in our own institution and on a national level. One solution to this problem is to provide general practitioners and obstetricians with a means to identify patients requiring gynecologic-oncology specialist referrals at the onset or at least prior to surgery. In our local setting, ovarian masses are typically discovered in patients presenting with symptoms (persistent abdominal bloating, indigestion, nausea, loss of appetite, feelings of pressure in the pelvis or lower back, needing to urinate more frequently, changes in bowel movements, increased abdominal girth, or easy fatigability) or as incidental findings on ultrasound. Pre-surgical screening is based on clinical and ultrasound features with the use of biochemical tumor markers limited to institutions and tertiary hospital settings. Most recently, the use of commercial multiplex assays combining various biomarkers and their accompanying malignancy risk calculation algorithms have been made available. These tests are increasing in utility worldwide as adjuncts to traditional screening methods but have yet to be maximized on a national level due to economic constraints and the lack of local experience.

**PRIMARY OUTCOMES**
The project will provide the following information based on a Filipino population: (1) Profile of women admitted for adnexal masses with an initial diagnosis of ovarian new growth (benign and malignant) in our institution. (2) A multivariable analysis (clinical, ultrasound, biochemical and histopathologic) of ovarian new growths in a Filipino population. (3) A local cost-utility analysis of multiple biomarker assays in the evaluation for ovarian cancer. (4) The construction of recommendations for the formulation of local practice guidelines concerning the use of biomarker assays in the pre-surgical evaluation of adnexal masses.

**KEY SECONDARY OUTCOMES**

Unspecified

**RECRUITMENT STATUS**

Recruiting

**COUNTRIES OF RECRUITMENT**

Philippines

**FDA DOCUMENT TRACKING NUMBER**

Unspecified

**FDA APPROVAL DATE**

0000-00-00

**ERC APPROVAL DATE**

2017-06-07

**FIRST ENROLMENT DATE**

2017-10-02

**TARGET SAMPLE SIZE (PHILIPPINES)**

380

**ACTUAL SAMPLE SIZE (PHILIPPINES)**

Unspecified

**REASON FOR THE DIFFERENCE BETWEEN TARGET & ACTUAL SAMPLE SIZES**

Unspecified

**DATE OF FIRST ENROLMENT**

2017-10-02

**KEY INCLUSION AND EXCLUSION CRITERIA (CT)**
Inclusion Criteria:
Must be over 18 years of age at OVERA testing
Diagnosed with an ovarian adnexal mass
Considered for surgery
Have not been referred to a Gynecologic-Oncologist prior to recruitment
Have not had cancer in the past five (5) years

Exclusion Criteria:
Patients with mental disabilities
Patients with severe co-morbidities
Patients who are pregnant.

STUDY TYPE
Observational

INTERVENTION NAME
Unspecified

INTERVENTION DESCRIPTION
Unspecified

AMENDMENT APPROVAL DATE/REASONS

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METHOD OF ALLOCATION
Randomized

MASKING / BLINDING
Single Blind

MASKING DETAILS
All women above 18 years of age who consult or are admitted at the University of the Philippines, Philippine General Hospital, Obstetrics and Gynecology Department for an ovarian adnexal mass, meet the inclusion criteria, and who do not have any of the exclusion criteria will be included in the study. Informed consent will be obtained. Each patient will undergo a physical examination and interview prior to standard ultrasonographic and Doppler evaluation. Ultrasonographic classification of the mass will be performed using the IOTA LR2 classification followed by OVERA blood sampling. Benign cases shall be randomized into either of two groups: disclosure or non-disclosure of OVERA results. For malignant cases and those in the benign disclosure group, OVERA testing results shall be given to consultants prior to treatment planning. All management decisions shall be documented per case. All surgery and histopathologic analysis shall be performed at the Philippine General Hospital. Data encoding, processing and analysis shall be done at the Department of Physiology, College of Medicine, University of the Philippines, Manila which is the official headquarters of the study. Management up to 1 year after the first OVERA test was performed shall be documented. A 6th and 12th month...
interval ultrasound shall be performed for all participants while repeat OVERA testing during this period shall be as follows: a) all patients diagnosed with cancer have 6th and 12th month interval follow up Overa testing; b) all patients who still have an adnexal mass because non-surgical treatment was chosen shall get repeat Overa testing done at 6th and 12th month intervals to help reevaluate cancer risk; and c) all patients who had surgery and a benign adnexal mass was removed will not undergo repeat Overa testing unless a new adnexal mass develops within the one year monitoring period.

ASSIGNMENT
Parallel

PURPOSE
To evaluate the clinical utility of biochemical markers in screening risk for ovarian cancer leading to more efficient management concerning:(1) surgical or non-surgical procedures(2) referral to Gynecologic Oncology Specialists(3) patient monitoring

PHASE
Not Applicable

RESEARCH UTILIZATION

<table>
<thead>
<tr>
<th>Utilization</th>
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<td>Oral Presentation</td>
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<td>Drug Literature</td>
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