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Evaluation of HE4 and CA125 serum markers to improve the risk determination of ovarian cancer in Malaysian women

Submission date 12/03/2014	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 04/04/2014	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 30/03/2016	**Condition category** Cancer	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
The poor survival rate in ovarian cancer is partly due to the lack of effective screening and also due to lack of symptoms in the early stage of the disease. Presence of the component CA125 in blood is the most widely used biomarker in ovarian cancer; however, it is not always increased in patients. The marker HE4 was best for detecting early stage ovarian cancer, and a combination of CA125 and HE4 provided a more accurate predictor of ovarian cancer than either marker alone. The purpose of this study is to evaluate the performance of HE4 alone and in combination with CA125 in Malaysian women to better predict malignant ovarian cancer in women presenting with a lump in the uterus (adnexal mass).

Who can participate?
Selected women who will undergo surgery for an adnexal mass will be enrolled for this study.

What does the study involve?
Each participant will give a blood sample before and after surgery, and a tissue sample taken during the surgery. Blood samples collected before surgery will be tested at the end of the patient enrolment. Clinical information such as age, menopausal status, risk factors for ovarian cancer, type of benign or malignant disease, and type and stage of cancer will be collected. For patients confirmed with diagnosis of ovarian cancer, a blood sample will be collected on a post-surgery follow-up visit and tested at the UMMC laboratory.

What are the possible benefits and risks of participating?
There is no immediate benefit from participating in the study; routine follow-up will be provided for those women diagnosed with and treated for malignant ovarian cancer. Future benefits to women with adnexal masses could be possible if the study the results show improved estimation of the risk of ovarian cancer, leading to a change in the diagnostic guidelines. No risk to participants are expected.

Where is the study run from?
This study will be conducted at University of Malaya Medical Centre (UMMC), in collaboration

with Universiti Kebangsaan Malaysia Medical Centre (UKMMC), Universiti Putra Malaysia (UPM) and Hospital Universiti Sains Malaysia (HUSM) for patient enrolment.

When is the study starting and how long is it expected to run for?
Recruitment of participants will happen over a period of 6 - 9 months, starting from July 2014. The study will end in December 2014.

Who is funding the study?
Abbott Laboratories (Singapore)

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
14-03-MYHE4

Study information

Scientific Title
HE4/ROMA (Risk of Ovarian Malignancy Algorithm) Evaluation Study in Malaysian Women

Study objectives
The measurement of HE4 in combination with CA125 in Malaysia women could improve the sensitivity and/or specificity for predicting malignant ovarian cancer in women presenting with an adnexal mass.

The null hypothesis is the HE4 serum marker and Risk of Ovarian Malignancy Algorithm (ROMA) adds no value to the current CA125 screening assay in women with an adnexal mass.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Ethics Committee Composition, University of Malaya Medical Centre, 23/04/2014

Study design
Blinded observational multi-center study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Ovarian cancer

Interventions
All women in this study will undergo surgery for their adnexal mass and the diagnosis will be based upon the final histopathological findings and stage according to FIGO (2009) classification.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. To evaluate ARCHITECT HE4/CA125 and ROMA values, measured at baseline, in estimating the risk of ovarian cancer in pre- and post-menopausal Malaysian women presenting with an adnexal mass.

2. To evaluate the performance of ARCHITECT HE4/CA125 and ROMA, measured at baseline, in discriminating benign and malignant pathologies in comparison to the ACOG/SGO pelvic mass referral guidelines in women with an adnexal mass.

Secondary outcome measures
1. Correlation of ARCHITECT HE4, ARCHITECT CA125, and ROMA values, collected at baseline, to the type and stages of malignancy in epithelial and mucinous ovarian cancers in samples.
2. Evaluation of the different combinations of guideline criteria collected at baseline to determine the best criteria for surgical referral of women with detected adnexal mass.
3. Projection of the impact of the different diagnostic algorithms' sensitivity and specificity on local healthcare costs or savings.

Overall study start date
15/04/2014

Completion date
31/12/2014

Eligibility

Key inclusion criteria
1. Malaysian females consenting to undergo surgery based on the finding of adnexal mass.
2. Adnexal mass must be verified by imaging.
3. Presence of at least one of the ACOG/SCO guideline criteria.
4. Able to understand and sign the Informed Consent forms. For females <18 years old, consent will be obtained from their parents or guardian.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
Minimum 400, maximum 600

Key exclusion criteria
1. Previous history of ovarian or primary peritoneal cancer
2. Subject previously confirmed with endometriosis
3. Any women with any known active malignancy
4. Subjects with previous bilateral oophorectomy
5. Subjects known to be pregnant
6. Subjects with end-stage renal failure
7. Subjects who previously underwent an organ transplantation

Date of first enrolment
01/07/2014

Date of final enrolment
31/12/2014

Locations

Countries of recruitment
Malaysia

Study participating centre
University of Malaysia Medical Center
Kuala Lumpur
Malaysia
50603

Sponsor information

Organisation
Abbott Laboratories (Singapore)

Sponsor details
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238467

Sponsor type
Industry

ROR
https://ror.org/00rhats79

Funder(s)

Funder type
Industry

Funder Name

Abbott Laboratories (Singapore)

Alternative Name(s)
Abbott, Abbott U.S., Abbott Alkaloidal Company

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration