Technology ALERT

Horizon Scanning Research & Intelligence Centre

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ROCA® for the diagnosis of ovarian cancer

TECHNOLOGY

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The Risk of Ovarian Cancer Algorithm, ROCA®, offered by Abcodia Ltd., is a new way of testing women for ovarian cancer. It is intended for use in postmenopausal women between 50 and 85; or women who are considered at higher risk of ovarian cancer by virtue of their family history of ovarian or breast cancer and/or a known genetic cause, such as inheritance of *BRCA1* or *BRCA2* mutations.

The ROCA® test is a quantitative algorithm that uses a woman's age, menopausal status, personal ovarian cancer risk status and serum CA125 levels. The ROCA® test compares a woman's individual longitudinal profile of the CA125 results over time, with the known profiles of women prior to diagnosis of ovarian cancer and women without ovarian cancer, to provide an accurate risk of having the disease.

The ROCA® test has been used in a multi-modal ovarian cancer screening strategy. The ROCA® test is used to triage women into one of three categories - normal, intermediate or elevated. A 'normal' score recommends another test in a year's time. An 'intermediate' score recommends a repeat test in three months and an 'elevated' score recommends that the woman receives a follow-up transvaginal ultrasound examination of the ovaries, a clinical assessment and a repeat CA125 screen. Results of the ROCA® test are sent back to the doctor within seven days of receiving the patient's blood sample.

The ROCA® test received a CE mark and launched a pilot service in July 2015.

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NHS National Institute for Health Research

POTENTIAL FOR IMPACT

Ovarian cancer is the leading cause of death from gynaecological cancer in the UK and has a generally poor outcome. This is because most women who have ovarian cancer present with advanced disease. This is in part due to early ovarian cancer being asymptomatic and also women not recognising the signs of ovarian cancer when they do present.

Current diagnosis involves clinical examination, ultrasound, CT scanning and biopsy. It also involves checking levels of CA125, the most frequently used biomarker for ovarian cancer detection, where levels of 35U/ml typically trigger further investigations. Around 90% of women with advanced ovarian cancer have elevated levels of CA125 in their blood serum. Monitoring CA125 blood serum levels is also useful for determining how ovarian cancer is responding to treatment.

As claimed by the company, the ROCA® test will triage women with significantly rising CA125 levels for further investigations, such as a trans-vaginal ultrasound scan and clinical assessment, while assigning normal testing frequency (blood test once yearly for post-menopausal women or every four months for high risk women) to women with stable CA125 levels.

The company state that the ROCA® test is unique in that each time a woman has the test, the ovarian cancer risk is recalculated using previous blood test results. According to the company, no other screening test does this.

From the UK Collaborative Trial of Ovarian Cancer Screening (UKCTOCS) multimodal screening results, the company claim that the ROCA® test may also be able to detect pre-symptomatic ovarian cancer when CA125 levels are very low. Currently, levels of CA125 below 35U/mL would not signal concern. ROCA® is reported to be sensitive enough to flag a change in the values of CA125 that could indicate the presence of cancer.

The ROCA® test may offer a new way of screening women for ovarian cancer and as a result detect early stage ovarian cancer, improving patient outcomes and survival. This technology is predicted to have an impact on the following domain of the NHS Outcomes Framework (www.england.nhs.uk/resources/resources-for-ccgs/out-frwrk):

Domain 1 Preventing people from dying prematurely.

EVIDENCE

PUBLISHED PAPERS AND ABSTRACTS

Menon U, Ryan A, Kalsi J *et al*. Risk algorithm using serial biomarker measurements doubles the number of screen-detected cancers compared with a single-threshold rule in the United Kingdom Collaborative Trial of Ovarian Cancer Screening (UKCTOCS). Journal of Clinical Oncology 2015;33(18):2061-2071.
http://www.ncbi.nlm.nih.gov/pubmed/25964255

Lu KH, Skates K, Hernandez MA *et al*. A 2-stage ovarian cancer screening strategy using the Risk of Ovarian Cancer Algorithm (ROCA) identifies early-stage incident cancers and demonstrates high positive predictive value. Cancer 2013;119(19):3453-3461.
http://www.ncbi.nlm.nih.gov/pubmed/23983047

Skates SJ. OCS: Development of the Risk of Ovarian Cancer Algorithm (ROCA) and ROCA screening trials. International Journal of Gynaecological Cancer 2012;22(Suppl1):S24-S26. http://www.ncbi.nlm.nih.gov/pmc/articles/3572791

Rosenthal AN, Fraser L, Philpott S *et al*., Results of 4-monthly screening in the UK Familial Ovarian Cancer Screening Study (UK FOCSS Phase 2). Presented at American Society of Clinical Oncology. Chicago, IL; 2013. http://meetinglibrary.asco.org/content/112237-132

RELEVANT PAPERS

Menon U, Gentry-Maharaj A, Hallet R *et al*. Sensitivity and specificity of multimodal and ultrasound screening for ovarian cancer, and stage distribution of detected cancers: results of the prevalence screen of the UK Collaborative Trial of Ovarian Cancer Screening (UKCTOCS). The Lancet Oncology 2009;10(4):327-340. http://www.ncbi.nlm.nih.gov/pubmed/19282241

COMPLETED UNPUBLISHED STUDIES

A ROCA trial in high-risk women was initiated in 2001 in the USA. It is a single-arm trial of 2,400 high-risk women aged 30 years or older, where CA125 tests are scheduled every 3 months. Results are expected in 2015.

Gynaecological Oncology Group 0199 was initiated in 2003 in the USA. It is a two-arm prospective study of women at high risk who choose between immediate risk-reducing salpingo-oophorectomy and screening with ROCA. Results are expected in 2015. http://www.ncbi.nlm.nih.gov/pmc/articles/3572791

ONGOING STUDIES

UK Collaborative Trial of Ovarian Cancer Screening (UKCTOCS).
http://www.instituteforwomenshealth.ucl.ac.uk/womens-cancer/gcrc/ukctocs

UK Familial Ovarian Cancer Screening Study (UKFOCSS).
http://www.instituteforwomenshealth.ucl.ac.uk/womens-cancer/gcrc/ukfocss

ADDITIONAL INFORMATION

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INFORMATION FROM

This Alert is based on information from the company and a time-limited internet search.