Prospective evaluation of Human Epididymal protein 4 (HE4) as predictor of malignancy in patients with a ovarian mass.

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The primary objective of this study is to evaluate the additional value of biomarker HE4, as second step after the RMI score, in the triage of patients with an ovarian mass. We aim to improve the referral process to oncological centers. Secondary…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Reproductive neoplasms female malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON47242

Source
ToetsingOnline

Brief title
HE4 Prediction

Condition

- Reproductive neoplasms female malignant and unspecified

Synonym
Ovarian cancer

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis

Source(s) of monetary or material Support: Fujirebio

Intervention

Keyword: HE4, Ovarian cancer, Prediction

Outcome measures

Primary outcome

The sensitivity and specificity with the addition of serum HE4 measurement, as 2nd step after calculation of the RMI score, for triage of patients with an ovarian mass.

Secondary outcome

Calculation of cost-effectiveness of addition of serum HE4 measurement.

Evaluation of impact of referral to an oncology center. Residual blood will be storred for future research. Possible implication will be the predictive value of cell-free tumor DNA (ctDNA).

Study description

Background summary

Correct characterization of an ovarian mass is important for the referral of patients with a high risk of malignancy, to a specialized oncologic center. Currently, the Risk of Malignancy Index (RMI), with a cut-off value of 200, is used in the Netherlands to select patients with a high risk of ovarian cancer. However, the sensitivity and specificity of the RMI score are not optimal. Currently, 40% of the referred patients have benign disease in the final pathology. This incorrect characterisation of the ovarian mass causes an increase in health care costs and may lead to anxiety in the patient because of the referral to an oncologic centre. Serum biomarker Human Epididymal protein 4 (HE4) is increased in patients with epithelial ovarian cancer and to a lesser extent in patients with a benign ovarian mass. Multiple retrospective studies have shown that mainly the specificity to distinguish a benign ovarian mass from ovarian cancer is improved when HE4 is used compared with CA125.

Study objective

The primary objective of this study is to evaluate the additional value of biomarker HE4, as second step after the RMI score, in the triage of patients with an ovarian mass. We aim to improve the referral process to oncological centers. Secondary outcomes are cost-effectiveness and impact of referral to an oncology center.

Study design

Prospective observational cohort study.

Study burden and risks

No risk or benefit for the specific patient. THe group of patients might benefit it a better triage of patients with an ovarian mass will be possible.

Contacts

Public
Antoni van Leeuwenhoek Ziekenhuis

Plesmanlaan 121
Amsterdam 1066CX
NL
Scientific
Antoni van Leeuwenhoek Ziekenhuis

Plesmanlaan 121
Amsterdam 1066CX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Age >=18 years
2. Presence of a complex ovarian mass
3. Understanding of Dutch or English language
4. Risk of malignancy score determined in referral hospital
5. General criteria:
a. Fit for laparotomy or laparoscopy to obtain a histologic diagnosis
b. Written informed consent
c. Normal Glomerular Filtration Rate (GFR): >60 ml/min/1,73 m2

Exclusion criteria

1. Age <18 years
2. Benign aspect of cyst including simple unilocular cyst for which RMI score is not calculated
3. Multiple malignancies at the same time
4. WHO performance status >= 3
5. Cancer already confirm in biopsy or ascites
6. Suspicion of extra-abdominal metastases

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-04-2017
Enrollment:	300

Type:	Actual

Ethics review

Approved WMO Date:	24-03-2017
Application type:	First submission
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	19-06-2017
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	12-01-2018
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	18-09-2018
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	11-10-2018
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	23-05-2019
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL58253.031.16