A study on the cost-effectiveness of risk scoring models for the discrimination between benign or malignant ovarian tumors

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Objective The objective of this study is to assess which risk scoring model is most cost-effective for the discrimination between benign and malignant ovarian tumors that guides referral decisions for women with ovarian tumors in the...

Ethical review	Positive opinion
Status	Recruiting
Health condition type	Reproductive neoplasms female malignant and unspecified
Study type	Observational non invasive

Summary

ID

NL-OMON23155

Source
NTR

Brief title
ACCEPT

Condition

- Reproductive neoplasms female malignant and unspecified

Health condition

Ovarian tumors

Research involving
Human

Sponsors and support

Primary sponsor: The Netherlands Organisation for Health Research and Development (ZonMW)
Source(s) of monetary or material Support: ZonMW

Intervention

- Other intervention

Explanation

Outcome measures

Primary outcome

Quality of Life (measured by the EuroQol-5D (EQ-5D)

Secondary outcome

Physical and mental health status (Short Form 12), Healthcare resource use costs (iMCQ instrument), Productivity losses (iPCQ instrument), Extend of cancer worries and anxiety (Cancer Worry Scale (CWS), Hospital Anxiety And Depression Scale (HADS), Intolerance of Uncertainty Scale (IUS 12) .

Study description

Background summary
Rationale

Correct referral of women with an ovarian tumor is still a major challenge. Annually, 6500 women undergo surgery for an ovarian tumor in the Netherlands of which a minority is malignant. It is important to accurately differentiate between benign and malignant ovarian tumors in order to reduce morbidity and mortality and make optimal use of scarce resources. There are several risk scoring models to guide referral decisions. Current cost-effectiveness analysis (CEAs) of the available risk scoring models do not deal with the impact of pre-operative misdiagnosis on women’s quality of life (QoL) and disutility due to incorrect referral as these data are not available yet. In the ACCEPT study this knowledge gap will be closed.

Hypothesis

The use of IOTA risk scoring models or subjective assessment by an expert (SA) to guide

referral decisions for women with ovarian tumors is more cost-effective than the use of the Risk of Malignancy Index (RMI) (usual care) as it will enhance correct referral which will improve QoL of women which will result in reduced costs and better use of healthcare budget in the Netherlands.

Study objective
Objective

The objective of this study is to assess which risk scoring model is most cost-effective for the discrimination between benign and malignant ovarian tumors that guides referral decisions for women with ovarian tumors in the Netherlands.

Study design
Study design

The study design is two-fold. First a prospective observational cohort study will be conducted to collect data on quality of life and resource use of women with an ovarian tumor at diagnosis, at hospital admission as well as 6 weeks and 3 months post hospital admission. Data will be collected by means of questionnaires and case report forms (CRF). Secondly a cost-effectiveness analysis will be performed in which different risk assessment models (the RMI, simple ultrasound-based rules (SR), Assessment of Different NEoplasias in the adneXa (ADNEX) and logistic regression model 2 (LR2) and subjective assessment (SA) will be compared. In total 584 women will be included.

Study population

Women (age >18 years) presenting in outpatient clinics of general hospitals with an ovarian tumor and indication for surgery will be included.

Data collection

No treatment or intervention will be performed. Data on quality of life and costs will be collected through questionnaires and CRFs. Data on the performance of the different risk assessment models will be retrieved from literature. With these data a decision analytic-model will be developed to compare the different risk assessment models.

Main study parameters/endpoints

Generic Quality of Life (QoL) measured by the EuroQol-5D (EQ-5D) to assess the impact of (in)correct referral on health-related QoL for women presenting with an ovarian tumor.

Secondary analysis

Secondary outcomes include physical and mental health status (Short Form 12), healthcare resource use costs (iMCQ instrument), productivity losses (iPCQ instrument), extend of cancer worries and anxiety (Cancer Worry Scale (CWS), hospital Anxiety And Depression Scale (HADS) and intolerance of Uncertainty Scale (IUS 12).

Intervention
This is an observational study. There are no interventions.

Contacts

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Eligibility criteria

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

Inclusion criteria

1. Age ≥ 18 years 2. Presentation in outpatient clinic of general hospital 3. Ovarian tumor with indication for surgery 4. Understanding of Dutch language

Exclusion criteria

1. Obvious benign ovarian tumor: a. Unilocular tumor with ground glass echogenicity in premenopausal woman suggestive of endometrioma b. Unilocular tumor with mixed echogenicity and acoustic shadows in premenopausal women (suggestive of benign cystic teratoma) c. Unilocular tumor with regular walls and maximal diameter < 10cm (suggestive

of simple cyst or cystadenoma) d. Remaining unilocular tumors with regular walls 2. Obvious malignant ovarian tumor: tumor with ascites and at least moderate color Doppler blood flow in postmenopausal women 3. Ovarian cancer or ovarian borderline tumor in medical history 4. Concurrent other malignancy

Study design

Design

Study phase:	N/A
Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	26-10-2023
Enrollment:	584
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Plan description
N/A

Ethics review

Positive opinion

Date:	11-06-2021
Application type:	First submission
Review commission:	METC Máxima Medisch Centrum

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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
NTR-new	NL9572
Other	METC Maxima Medisch Centrum : N21.056

Study results