Implementation of the IOTA-models in The Netherlands: current status and possibilities for improvement

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26540

Source
Nationaal Trial Register

Health condition

Ovarian carcinoma

Sponsors and support

Primary sponsor: Maxima Medical Center, Veldhoven, The Netherlands
Source(s) of monetary or material Support: Maxima Medisch Centrum, Veldhoven, The Netherlands

Intervention

Outcome measures

Primary outcome

Percentage of hospitals using the IOTA models

Secondary outcome

Contentment with the various IOTA models, impeding and promoting factors for

implementation.

Study description

Background summary

Background and problem statement
The current triage method to differentiate between benign and malignant ovarian tumors has poor sensitivity. As a consequence, many women are not diagnosed or are diagnosed at a late stadium with ovarian cancer, resulting in a poor prognosis for these women with a 5-year survival of 24%. The International Ovarian Tumor Analysis (IOTA) models are a favourable alternative radiological triage method with better sensitivity and similar or even better cost-effectiveness. However, the superiority of the IOTA-models compared to the current method based on the Risk of Malignancy Index (RMI) has not yet been translated into an adjustment of the guidelines and broad implementation.

Research question
How can the implementation of the IOTA models be improved by gynaecologists in The Netherlands?

Secondary research questions are formulated to gather information on the current implementation status of the IOTA models, the impeding and promoting factors for implementation of the IOTA models and a plan of action to improve the implementation of the IOTA models.

Setting of the research and subjects
The research will be performed at the Maxima Medical Center (MMC) in The Netherlands and will focus on Dutch healthcare.

Methods of data collection
Of every Dutch general and academic hospital one contact person will be approached to participate in a digital questionnaire to gather quantitative data about the current implementation status of the IOTA models. A semi-structured interview will be conducted with a representative sample of 14 contact persons to obtain qualitative data about impeding and promoting factors for implementation. In addition, participants of the IOTA course of 2018 and 2019 will be approached for a small prospective explorative research to obtain information about the learning process of making ultrasounds according to the IOTA models.

Methods of data analysis
The quantitative data will be processed in Excel and SPSS files. Data from the semi-structured interviews will be transcribed, coded and processed in a descriptive analysis. The results of the research about the learning process will be related to the exposure in recent years by means of a descriptive analysis. With the results of all subquestions a concrete plan of action that can be undertaken to improve the implementation of the IOTA models in the Netherlands will be written and shared with the NVOG.

Study objective

The current implementation status of the IOTA-models is suboptimal and below the target of 80%. The research will provide insight in the exact implementation status of the IOTA-models in The Netherlands and impeding and promoting factors for implementation.

Study design

The questionnaires will be distributed in the beginning of 2021. The aim is to conduct the semi-structured interviews in the first months of 2021. In the second quarter of 2021, the results from the questionnaires and the semi-structured interviews will be analyzed and processed in a thesis and report to the NVOG.

Intervention

None

Contacts

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Eligibility criteria

Inclusion criteria

Gynaecologists in general and academic Dutch hospitals.

Exclusion criteria

Gynaecologists working in a private clinic or outside The Netherlands.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	14-12-2020
Enrollment:	80
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type:	Not applicable

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	NL9167
Other	METC Maxima Medisch Centrum : N20.121

Study results