Geriatric screening in the treatment of elderly patients with ovarian carcinoma

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28593

Source
Nationaal Trial Register

Brief title
GERSOC

Health condition

English: ovarian carcinoma, ovarian cancer
Dutch: ovariumcarcinoom, eierstokkanker

Sponsors and support

Primary sponsor: The Netherlands Cancer Institute - Antoni van Leeuwenhoek Hospital (NKI-AVL)
Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

Primary endpoints include the percentage of started and completed therapies (standard as well as adapted) in 'geriatric screening care' and 'care as usual' and the difference in percentage in completed treatment in both groups.

Secondary outcome

Secondary endpoints include health related quality of life; toxicity of treatment; progression free- and overall survival and cost-effectiveness in terms of incremental costs per quality adjusted life year from a societal perspective.

Study description

Background summary

Introduction: Advanced stage ovarian cancer is treated with combination chemotherapy and cytoreductive surgery. However, 40% of ovarian cancer patients is over 70 years of age and in many elderly patients treatment is withheld or stopped prematurely due to frailty and/or toxicity. It remains difficult to differentiate patients who are fit for standard treatment from patients who may need an adjusted treatment. The use of geriatric screening tests might improve identification of elderly patients who need further geriatric evaluation to improve tailored therapy of frail older patients.

Aim: To increase the percentage of elderly patients with ovarian cancer who complete standard or adapted therapy by using geriatric screening prior to start of therapy.

Study population: Patients aged 70 years and older who are newly diagnosed with ovarian cancer FIGO-stage II - IV.

Methods: This study is a pragmatic, cluster randomized controlled trial in 20 hospitals in the Netherlands. Patients with newly diagnosed ovarian cancer are included prior to start of treatment with a follow-up of 24 months. Hospitals will be randomized to either geriatric screening care or care as usual. In geriatric screening care, two geriatric screening tests (G8-questionnaire and Timed Up and Go-test (TUG)) will be performed prior to start of treatment. Patients determined unfit are referred to a geriatrician for geriatric assessment and treatment advise. In care as usual, treatment decisions will be made on information from usual history taking and physical examination.

Main study parameters/endpoints: Primary endpoints include the percentage of started and completed (standard and adapted) therapy in patients with either geriatric screening care or care as usual. Secondary endpoints include health related quality of life; toxicity; progression free survival; overall survival and cost-effectiveness in terms of incremental costs per QALY from a societal perspective.

Study objective

Incorporation of geriatric screening tests into work-up for ovarian cancer therapy might improve completion of treatment in this population and prevent overtreatment of frail elderly patients.

Study design

- T=0: baseline characteristics
- T=0, 6, 12 and 24 months after diagnosis: quality of life and resource use (EORTC-C30, EORTC-OV28, EuroQol-5D-5L, abbreviated version of the iMCQ)
- T=24 months after diagnosis: survival, percentage started and completed treatment

All other data related to the trial will be collected during follow-up.

Intervention

This study is a pragmatic, cluster randomized controlled trial. More than twenty hospitals in the Netherlands will be randomized to either 'geriatric screening care' or 'care as usual'.

In 'geriatric screening care', two geriatric screening tests will be performed during intake (G8-questionnaire and TUG). When determined unfit, patients are referred to a geriatrician for geriatric assessment and treatment advise. This group will be compared to 'care as usual' in which the decision to start, adapt or omit standard treatment will be made on information from usual history taking and physical examination.

Contacts

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Eligibility criteria

Inclusion criteria

- A woman diagnosed with primary ovarian/fallopian/peritoneal carcinoma FIGO stage II, III or IV OR
- A woman with a high suspicion of primary ovarian/fallopian/peritoneal carcinoma FIGO stage II, III or IV (a high suspicion of advanced stage ovarian/fallopian/peritoneal carcinoma should be based on imaging suggesting evidence of metastasized disease (i.e. signs of pelvic, abdominal or extra-abdominal metastases))
- Aged 70 years or older
- Able to complete a Dutch questionnaire
- Written and signed informed consent

Exclusion criteria

- Not being able to read or write Dutch, as they are not able to complete a Dutch questionnaire

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-08-2017
Enrollment:	320
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion
Date: 02-08-2017
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 50441
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL6745
NTR-old	NTR6923
CCMO	NL62356.031.17
OMON	NL-OMON50441

Study results