Geriatric screening in the treatment of elderly patients with ovarian carcinoma

Published: 14-12-2017
Last updated: 30-01-2025

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

Summary

ID

NL-OMON50441

Source
ToetsingOnline

Brief title
GERSOC (GERiatric Screening of elderly patients with Ovarian Carcinoma)

Condition

- Reproductive neoplasms female malignant and unspecified

Synonym
Ovarian cancer, ovarian carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: Geriatric screening, Ovarian carcinoma, Quality of life

Outcome measures

Primary outcome

Primary outcome parameters are the percentage started and completed treatment in *geriatric screening care* and *care as usual* and the difference in percentage in completed treatment (either standard or adapted) between 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

Treatment of advanced stage ovarian cancer consists of cytoreductive surgery in combination with chemotherapy. Forty percent of patients diagnosed with ovarian cancer is >= 70 years of age. Data shows treatment is started less frequently with increasing age. Also, 1:4 older patients who has started treatment was unable to finish this intensive therapy, resulting in loss of quality of life without survival benefit. It remains difficult to differentiate patients who are fit for standard treatment from those who may benefit from adjusted treatment. Geriatric assessment is thought to improve tailored therapy for vulnerable patients. Incorporation of geriatric screening tests into work-up for ovarian cancer therapy might improve completion of treatment in this population.

Study objective

The primary objective is 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 and to assess whether geriatric screening tests provide a better identification of patients who are fit for standard treatment or who need an adapted treatment.

Secondary objectives include identifying toxicity, quality of life, survival and cost-effectiveness of the addition of geriatric screening to ovarian cancer therapy.

Study design

This study is a pragmatic, cluster randomized controlled trial. Twenty hospitals will be randomized to either usual care or geriatric screening care. In this longitudinal study, patients are included immediately after initial diagnosis of ovarian cancer with a follow-up of 24 months. A total of 320 patients will be included in the study.

Geriatric screening care: two geriatric screening tests (TUG and G8-questionnaire) are performed before a treatment strategy is defined. Patients scoring unfit will be referred to a geriatrician, resulting in a adapted treatment strategy. When scored fit, patients will receive standard treatment.
Care as usual: care is provided in agreement with the Dutch guidelines.

Data on health related quality of life and resource use will be obtained by means of questionnaires at four points in time: before, during and after treatment. Clinical, socioeconomic and resource use data will be collected from patient files.

Study burden and risks

Patients are asked to complete four sets of four questionnaires concerning quality of life on T=0, T=6, T=12 and T=24 months after initial diagnosis. Patients in *geriatric screening care* receive two short geriatric screening tests (+/- 10 minutes) and are referred to a geriatrician when considered necessary. The questionnaires and the geriatric screening tests are considered safe and not very burdensome. No major risk are expected. Elderly patients with ovarian cancer as a group are considered to benefit from the study in the future.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- A woman with high suspicion of OR newly diagnosed with ovarian cancer FIGO stage II, III or IV
- 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:	Observational non invasive
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	24-07-2018
Enrollment:	320
Type:	Actual

Ethics review

Approved WMO Date:	14-12-2017
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	21-03-2018
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	30-03-2018
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	26-04-2018
Application type:	Amendment
Review commission:	METC NedMec

Approved WMO

Date:	24-08-2018
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	15-11-2018
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	28-03-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	02-05-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	20-08-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	12-12-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	27-08-2020
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	30-12-2020
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	02-11-2021
Application type:	Amendment
Review commission:	METC NedMec

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 28593
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL62356.031.17
Other	NTR-nummer: NL6745