Value of Comprehensive Geriatric Assessment, clinical judgment, and performance status in the treatment of patients with epithelal ovarian carcinoma aged 70 years and older.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23843

Source
Nationaal Trial Register

Brief title
CGA-trial

Health condition

Ovarian cancer FIGO IIB-IV

Sponsors and support

Primary sponsor: TweeSteden hospital, location Tilburg

Intervention

Outcome measures

Primary outcome

Able to undergo chemotherapeutic regime.

Secondary outcome

1. Mortality;

2. Functional decline;

3. Preserved mobility.

Study description

Background summary

Objective:

To correlate clinical course, outcome of the disease and toxicities with clinical judgment and CGA in order to better define which components can support future decisions with regard to patient selection and treatment.

Study objective

1. Comprehensive geriatric assessment has no benefits in selecting patients fit for chemotherapeutic treatment, compared to clinical judgement by the medical oncologist;

2. Observational report of the functional outcome of treating ovarian carcinoma in the elderly.

Study design

N/A

Intervention

CGA, using predefined cutoff points in MMSE, ADL-score, IADL-score en comorbidity-index.

Contacts

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Eligibility criteria

Inclusion criteria

1. Histological confirmed (extra) epithelial ovarian carcinoma FIGO IIB - IV. Tumors of borderline malignancy are excluded;

2. No prior treatment with cytostatic agents or radiotherapy;

3. Age ¡Ý 70 years;

4. Performance status 0-2;

5. Life expectancy ¡Ý 3 months;

6. Able to undergo protocol treatment according to clinical judgment of the medical oncologist;

7. No second primary malignancy except for adequately treated in situ carcinoma of the cervix uteri, basal or squamous cell carcinoma of the skin, or a prior cancer cured with surgery alone and with a disease-free interval of longer than 5 years;

8. Adequate hematological, renal and hepatic function as defined by the following required laboratory values (obtained ¡Ü 14 days prior to study enrollment):

a. WBC ¡Ý 3.0x109/L;

b. Platelets ¡Ý 100x109/L;

c. Calculated creatinine clearance ¡Ý 40 ml/min (according to the Cockroft and Gault formula), see 9.3;

d. Serum bilirubin ¡Ü 1.5 x upper normal limit;

e. SGOT (AST) and/or SGPT (ALT) ¡Ü 2.5 x upper normal limit;

9. Absence of significant cardiac disease, i.e. uncontrolled high blood pressure, unstable angina, congestive heart failure, myocardial infarction within the previous year, or cardiac ventricular arrhythmias requiring medication. History of 2nd and 3rd degree heart blocks without pacemaker in situ;

10. No active infection, major medical illness, signs or symptoms of CNS involvement or leptomeningeal disease;

11. No known hypersensitivity reactions to any of the components of the treatment, including cremophor;

12. Absence of CTC grade ¡Ý 1 peripheral neurotoxicity;

13. Assessable for treatment and follow-up;

14. Informed consent.

Exclusion criteria

No exclusion criteria mentioned in the protocol.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	N/A: single arm study
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-05-2004

Enrollment:	60
Type:	Actual

Ethics review

Positive opinion Date:	27-09-2005
Application type:	First submission

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	NL405
NTR-old	NTR445
Other	CCMO : P03.1456 L
ISRCTN	ISRCTN79708370

Study results

Summary results
Maas HA, Kruitwagen RF, Lemmens VE, Goey SH, Janssen-Heijnen ML.
Gynecol Oncol. 2005 Apr;97(1):104-9
The influence of age and co-morbidity on treatment and prognosis of ovarian cancer: a population-based study.