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

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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...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23843

Bron
NTR

Verkorte titel
CGA-trial

Aandoening

Ovarian cancer FIGO IIB-IV

Ondersteuning

Primaire sponsor: TweeSteden hospital, location Tilburg

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Able to undergo chemotherapeutic regime.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

No exclusion criteria mentioned in the protocol.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland
Status: Werving gestopt

(Verwachte) startdatum:	01-05-2004
Aantal proefpersonen:	60
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	27-09-2005
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL405
NTR-old	NTR445
Ander register	CCMO : P03.1456 L
ISRCTN	ISRCTN79708370

Resultaten

Samenvatting resultaten
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.