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

**Submission date**
26/02/2007

**Recruitment status**
No longer recruiting

**Registration date**
26/02/2007

**Overall study status**
Completed

**Last Edited**
20/10/2008

**Condition category**
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**Protocol serial number**
CCMO no.: P03.1456 L; NTR445

## Study information

## Scientific Title

## Acronym
CGA-trial

## Study objectives
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

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Approval received from the local ethics board (Medisch-Ethische Toetsing Onderzoek patienten en Proefpersonen [METOPP]) on the 26th October 2003, approval amendement 22nd August 2005 (ref: P03.1456L).

## Study design
Observational multicentre trial

## Primary study design
Observational

## Study type(s)
Quality of life

## Health condition(s) or problem(s) studied
Ovarian cancer

## Interventions
CGA, using predefined cutoff points in Mini Mental State Examination (MMSE), Activities of Daily Living (ADL)-score, Instrumental Activities of Daily Living (IADL)-score and comorbidity-index.

## Intervention Type
Other

## Phase
Not Specified

## Primary outcome(s)
Able to undergo chemotherapeutic regime.

## Key secondary outcome(s))
1. Mortality
2. Functional decline
3. Preserved mobility

## Completion date

01/05/2007

# Eligibility

### Key inclusion criteria
1. Histological confirmed (extra) epithelial ovarian carcinoma International Federation of Gynaecology and Obstetrics (FIGO) grade IIB - IV. Tumours of borderline malignancy are excluded.
2. No prior treatment with cytostatic agents or radiotherapy
3. Age greater than or equal to 70 years
4. Eastern Cooperative Oncology Group (ECOG) performance status zero to two
5. Life expectancy greater than or equal to three 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 five years
8. Adequate haematological, renal and hepatic function as defined by the following required laboratory values (obtained less than or equal to 14 days prior to study enrolment):
8.1. White blood cells (WBC) greater than or equal to 3.0 x 10^9/L
8.2. Platelets greater than or equal to 100 x 10^9/L
8.3. Calculated creatinine clearance greater than or equal to 40 ml/min (according to the Cockroft and Gault formula)
8.4. Serum bilirubin less than or equal to 1.5 x upper normal limit
8.5. Serum glutamic oxaloacetic transaminase (SGOT) (aspartate aminotransferase [AST]) and/or serum glutamic pyruvic transaminase (SGPT) (alanine aminotransferase [ALT]) less than or equal to 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 second and third degree heart blocks without pacemaker in situ.
10. No active infection, major medical illness, signs or symptoms of central nervous system (CNS) involvement or leptomeningeal disease
11. No known hypersensitivity reactions to any of the components of the treatment, including cremophor
12. Absence of common toxicity criteria (CTC) grade greater than or equal to one peripheral neurotoxicity
13. Assessable for treatment and follow-up
14. Informed consent

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Senior

### Sex
Female

**Key exclusion criteria**
Does not comply with the above inclusion criteria

**Date of first enrolment**
01/05/2004

**Date of final enrolment**
01/05/2007

# Locations

**Countries of recruitment**
Netherlands

**Study participating centre**
**TweeSteden Hospital**
Tilburg
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5000 LA

# Sponsor information

**Organisation**
TweeSteden Hospital (The Netherlands)

**ROR**
https://ror.org/04gpfvy81

# Funder(s)

**Funder type**
Industry

**Funder Name**
Amgen Europe B.V. (The Netherlands)

**Funder Name**
Bristol-Myers Squibb (USA)

**Alternative Name(s)**

Bristol-Myers Squibb Company, Bristol Myers Squibb, Bristol-Myers Company, BMS

### Funding Body Type
Government organisation

### Funding Body Subtype
For-profit companies (industry)

### Location
United States of America

### Funder Name
TweeSteden Hospital (The Netherlands)

## Results and Publications

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary