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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	[_] Prospectively registered [_] Protocol
Registration date 26/02/2007	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 20/10/2008	**Condition category** Cancer	[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Multi-centre

Study setting(s)
Not specified

Study type(s)
Quality of life

Participant information sheet

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 measure
Able to undergo chemotherapeutic regime.

Secondary outcome measures
1. Mortality
2. Functional decline
3. Preserved mobility

Overall study start date
01/05/2004

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

Age group
Senior

Sex
Female

Target number of participants
60

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
Netherlands
5000 LA

Sponsor information

Organisation
TweeSteden Hospital (The Netherlands)

Sponsor details
Location Tilburg
P.O. Box 90107
Tilburg

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5000 LA

Sponsor type
Hospital/treatment centre

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, 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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration