

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

Submission date 26/02/2007	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 26/02/2007	Overall study status Completed	☐ Protocol
Last Edited 20/10/2008	Condition category Cancer	☐ 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 patiënten en Proefpersonen [METOPP]) on the 26th October 2003, approval amendment 22nd August 2005 (ref: P03.1456L).

Primary study design

Observational

Study design

Observational multicentre trial

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 $3.0 \times 10^9/L$
 - 8.2. Platelets greater than or equal to $100 \times 10^9/L$
 - 8.3. Calculated creatinine clearance greater than or equal to 40 ml/min (according to the Cockcroft 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

Netherlands

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