GLOBAL STUDY TO ASSESS THE ADDITION OF BEVACIZUMAB TO CARBOPLATIN AND PACLITAXEL AS FRONT-LINE TREATMENT OF EPITHELIAL OVARIAN CANCER, FALLOPIAN TUBE CARCINOMA OR PRIMARY PERITONEAL CARCINOMA

Published: 05-10-2010
Last updated: 04-05-2024

Zie pagina 39-40 van het protocol MO22923 versie 2, 26 Mei 2011

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Reproductive neoplasms female malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON39830

Source
ToetsingOnline

Brief title
ROSiA

Condition

- Reproductive neoplasms female malignant and unspecified
- Ovarian and fallopian tube disorders

Synonym
ovariancancer, ovariancarcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Roche Nederland B.V.
Source(s) of monetary or material Support: Roche Nederland B.V.

Intervention

Keyword: bevacizumab, chemotherapy, ovarian cancer, safety

Outcome measures

Primary outcome

Zie pagina 39 van het protocol MO22923 versie 2, 26 Mei 2011

Secondary outcome

Zie pagina 39 van het protocol MO22923 versie 2, 26 Mei 2011

Study description

Background summary

Zie pagina 31-39 van het protocol MO22923 versie 2, 26 Mei 2011

Study objective

Zie pagina 39-40 van het protocol MO22923 versie 2, 26 Mei 2011

Study design

Zie pagina 40-43 van het protocol MO22923 versie 2, 26 Mei 2011

Intervention

Zie pagina 50-61 en tabel 1 van het protocol MO22923 versie 2, 26 Mei 2011

Study burden and risks

The following assessments will be done: Intravenous administration of study medication, physical examination, heart rate and blood pressure measurement, blood and urine tests, pregnancy (if applicable), ECG, CT scans. There is a risk of unknown side effects. Drawing blood samples may cause bruising (black and blue marks) and discomfort where the blood was taken. There is also a

possibility of infection or blood clots at the site where the blood was taken. There is a potential risk of radiation exposure from CT scans; however, this risk is considered small. Chemotherapy can possible lead to nausea or vomiting, leucocytopenia, thrombocytopenia, fatigue, allergic reactions (to paclitaxel), hair loss, joint pain, muscle pain, damage to nerves of blood vessels, causing mood swings, mouth ulcers, pigmentation and cause thrombosis. Bevacizumab can lead to hypertension, numbness, or loss of sensation in the fingers or toes, leucotytopenia, possible accompanied by fever, thrombocytopenia, shortness of breath, diarrhea, rectal bleeding, nausea and vomiting, pain (including headaches and joint pain), constipation inflammation of mucous membranes or mouth inflammation, protein in urine, bleeding from mucous membranes (such as nasal bleeding), lack of energy, weakness, loss of appetite, fever, runny nose, dry skin, scaling and inflammation of the skin, change in the color of the skin, change in taste perception and problems with eyes.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- Female patients, >/=18 years of age;- Histologically confirmed epithelial ovarian carcinoma, fallopian tube carcinoma, primary peritoneal carcinoma or clear cell carcinoma or carcinosarcoma. Patients with recurrent ovarian cancer who have been previously treated with surgery alone for their early stage disease are eligible.;- Eastern Cooperative Oncology Group Performance Status (ECOG PS) of 0, 1 or 2;- Life expectancy >/=3 months

Exclusion criteria

- Patients with non-epithelial ovarian cancer, ovarian tumors with low malignant potential (i.e. borderline tumors), or synchronous primary endometrial carcinoma;- Previous systemic therapy for ovarian cancer. Prior neo-adjuvant chemotherapy is allowed;- Planned intraperitoneal cytotoxic chemotherapy;- Radiotherapy within 28 days of Day 1, Cycle 1;- Major surgical procedure, open biopsy or significant traumatic injury within 28 days prior to first dose of Avastin;- History or evidence of NCI CTCAE Grade >=1 arterial thromboembolic event or Grade >=3 venous thromboembolic event within the 6 months prior to enrolment

Study design

Design

Study phase:	3
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	17-01-2011
Enrollment:	40
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Avastin
Generic name:	bevacizumab
Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	carboplatin
Generic name:	platinum
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	paclitaxel
Generic name:	taxol
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	05-10-2010
Application type:	First submission
Review commission:	METC Noord-Holland (Alkmaar)
Approved WMO Date:	06-12-2010
Application type:	First submission
Review commission:	METC Noord-Holland (Alkmaar)
Approved WMO Date:	27-12-2010
Application type:	Amendment
Review commission:	METC Noord-Holland (Alkmaar)
Approved WMO Date:	07-01-2011
Application type:	Amendment
Review commission:	METC Noord-Holland (Alkmaar)
Approved WMO Date:	17-01-2011

Application type:	Amendment
Review commission:	METC Noord-Holland (Alkmaar)
Approved WMO Date:	03-08-2011
Application type:	Amendment
Review commission:	METC Noord-Holland (Alkmaar)
Approved WMO Date:	09-09-2011
Application type:	Amendment
Review commission:	METC Noord-Holland (Alkmaar)
Approved WMO Date:	16-01-2012
Application type:	Amendment
Review commission:	METC Noord-Holland (Alkmaar)
Approved WMO Date:	05-03-2012
Application type:	Amendment
Review commission:	METC Noord-Holland (Alkmaar)
Approved WMO Date:	22-05-2012
Application type:	Amendment
Review commission:	METC Noord-Holland (Alkmaar)
Approved WMO Date:	04-06-2012
Application type:	Amendment
Review commission:	METC Noord-Holland (Alkmaar)
Approved WMO Date:	17-09-2012
Application type:	Amendment
Review commission:	METC Noord-Holland (Alkmaar)
Approved WMO Date:	24-09-2012
Application type:	Amendment
Review commission:	METC Noord-Holland (Alkmaar)
Approved WMO Date:	15-02-2013

Application type:	Amendment
Review commission:	METC Noord-Holland (Alkmaar)
Approved WMO Date:	10-06-2013
Application type:	Amendment
Review commission:	METC Noord-Holland (Alkmaar)
Approved WMO Date:	21-01-2014
Application type:	Amendment
Review commission:	METC Noord-Holland (Alkmaar)
Approved WMO Date:	31-01-2014
Application type:	Amendment
Review commission:	METC Noord-Holland (Alkmaar)
Approved WMO Date:	14-04-2014
Application type:	Amendment
Review commission:	METC Noord-Holland (Alkmaar)
Approved WMO Date:	30-04-2014
Application type:	Amendment
Review commission:	METC Noord-Holland (Alkmaar)
Approved WMO Date:	30-01-2015
Application type:	Amendment
Review commission:	METC Noord-Holland (Alkmaar)

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
EudraCT	EUCTR2010-019525-34-NL
CCMO	NL33812.094.10