

An open-label, multicenter, randomized Phase II Study to compare the effects of Paclitaxel /Carboplatin and Lonafarnib to those of Paclitaxel/Carboplatin for 1st line Treatment of patients with epithelial ovarian cancer International Federation of Gynecology and Obstetrics (FIGO) Stages IIB-IV

Submission date 12/07/2005	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 23/08/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 02/07/2012	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Study website
<http://www.ago-ovar.de>

Contact information

Type(s)
Scientific

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65199

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

AGO-OVAR 15

Study information

Scientific Title

Acronym

AGO-OVAR 15

Study objectives

Standard chemotherapy for ovarian cancer patients after primary cytoreductive surgery is paclitaxel in combination with carboplatin. Several phase III studies are evaluating the efficacy of a third drug within this standard trial either as a combined or as a consolidation therapy. The final results of these studies have not yet been published. The addition of farnesyltransferase (FT) inhibitors or epidermal growth factor inhibitors to primary chemotherapy are very promising approaches to optimize primary therapy. Lonafernib is a FT inhibitor that is active against a broad spectrum of tumor cell lines in vitro and tumor xenografts in nude mice. Lonafernib has single agent antitumor activity as well as enhanced activity in combination with taxanes in a number of tumor cell lines and mice models. Based upon positive results from clinical studies demonstrating enhanced activity when combining taxanes with lonafernib, combination therapy of paclitaxel and carboplatin with lonafernib is expected to have greater efficacy than standard therapy or FTI therapy alone in primary ovarian cancer patients.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Multi-centre

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Epithelial Ovarian Cancer, First-Line Treatment

Interventions

Paclitaxel/Carboplatin +/- LonaFarnib

The previous sponsor for this trial (until November 2009) was:

MedServ. GmbH (Germany)

Ludwig-Erhard-Str. 100,

65199 Wiesbaden

Germany

Intervention Type

Drug

Phase

Phase II

Drug/device/biological/vaccine name(s)

Paclitaxel/Carboplatin and LonaFarnib

Primary outcome measure

Comparison of the effect (progression-free survival [PFS]) of paclitaxel/carboplatin and lonaFarnib to that of paclitaxel/carboplatin in patients with previously untreated epithelial cancer of the ovary FIGO stages IIBIV. The primary purpose of this study is to determine whether the additional effect of lonaFarnib is sufficient to conduct a phase III study.

Secondary outcome measures

The secondary objectives are to evaluate response to treatment and overall survival, and to assess the safety in both treatment arms and to assess exposure (PK) and PD of lonaFarnib.

Overall study start date

01/09/2005

Completion date

30/09/2006

Eligibility

Key inclusion criteria

1. Previously untreated patients with a histologically confirmed diagnosis of cancer of the ovary or the fallopian tube or extra-ovarian papillary serous tumors
FIGO stage IIBIV regardless of measurable or non-measurable disease
2. Age ≥ 18 years
3. Eastern Cooperative Oncology Group (ECOG) performance status ≤ 2
4. Life-expectancy of at least 6 months

5. Adequate bone marrow, renal and hepatic function defined as white blood cell count (WBC) $>3.0/\text{nl}$, Neutrophils (ANC) $\geq 1.5/\text{nl}$, Platelets $\geq 100/\text{nl}$, Hemoglobin $>6 \text{ mmol/l}$ ($>10.0 \text{ g/dl}$), Bilirubin $\leq 1 \times$ upper limit of normal range
6. Aspartate aminotransferase (AST) and alanine aminotransferase (ALT) $<1.5 \times$ upper limit of normal range
7. Alkaline phosphatase $<2.5 \times$ upper limit of normal range
8. Estimated glomerular filtration rate GFR $\geq 50 \text{ ml/min}$ according to Jelliffe or Cockcroft-Gault formula
9. Patients who have given their signed and written informed consent to participate in the trial after fully understanding the implication and constraints of the protocol
10. Patients must be geographically accessible for treatment and follow-up
11. Time between definitive surgery and randomization ≥ 6 weeks

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

100

Key exclusion criteria

1. Ovarian tumors of low malignant potential (borderline tumors)
2. Non-epithelial ovarian or mixed epithelial/non epithelial tumors (e.g. mixed Mullerian tumors)
3. Patients who have received previous chemotherapy or radiotherapy
4. Prior treatment with FT inhibitors
5. Patients with a prior diagnosis of any malignancy not cured by surgery alone less than 5 years before study entry (except in situ carcinoma of the cervix or adequately treated basal cell carcinoma of the skin)
6. Complete bowel obstruction or the presence of symptomatic brain metastases
7. Concurrent severe medical problems unrelated to malignancy which would significantly limit full compliance with the study or expose the patient to extreme risk or decreased life expectancy
8. Patients with a history of seizure disorder or central nervous system disorders
9. Pre-existing motor or sensory neurologic pathology or symptoms $>$ National Cancer Institute - Common Toxicity Criteria (NCI-CTC) grade 1
10. History of congestive heart failure (New York Heart Association [NYHA] Classification >2), even if medically controlled
11. History of clinical and electrocardiographically documented myocardial infarction within the last 6 months
12. History of atrial or ventricular arrhythmias (\geq LOWN II)
13. Patients with significant Fridericia QTc (QTcF) prolongation at Baseline (i.e. QTcF $>470 \text{ msec}$)
14. Patients with severe active infection
15. Patients with a history of severe hypersensitivity reactions to products containing Cremophor EL (cyclosporin or vitamin K) and/or patients with known hypersensitivity to

compounds chemically related to Carboplatin and Paclitaxel

16. Fertile women not using adequate contraceptive methods

17. Women who are pregnant or breast feeding

18. Administration of other anticancer therapy or simultaneous chemotherapeutic and/or hormonal drugs, or radiotherapy during the study treatment period (except: hormonal replacement therapy and/or steroid antiemetics)

19. Patients who have used any investigational drugs within 30 days of study entry

20. Patients who are participating in any other clinical study

21. Dementia or significantly altered mental status that would prohibit the understanding and giving of informed consent

Date of first enrolment

01/09/2005

Date of final enrolment

30/09/2006

Locations

Countries of recruitment

Germany

Study participating centre

Ludwig-Erhard-Str. 100

Wiesbaden

Germany

65199

Sponsor information

Organisation

AGO Research GmbH (Germany)

Sponsor details

Kaiser-Friedrich-Ring 71

Wiesbaden

Germany

65185

Sponsor type

Industry

Website

<http://www.ago-ovar.de>

ROR

<https://ror.org/01jdhsq12>

Funder(s)

Funder type

Charity

Funder Name

AGO Ovarian Cancer Study Group (AGO-OVAR)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2012		Yes	No