DESKTOP III Summary

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DESKTOP III - A randomized multicenter study to compare the efficacy of additional tumour debulking surgery versus chemotherapy alone for recurrent platinum-sensitive ovarian cancer

Background:

Previous studies have shown significant survival benefit in those with complete macroscopic cytoreduction whilst the AGO score appears to reliably predict complete resectability in this population of patients.

However, it is unclear if both the AGO score or complete resectability at late cytoreduction merely reflect a less aggressive biological variable of the tumour and thus might achieve the same outcome with chemotherapy alone. The alternative is that surgery confers a real benefit.

Aims:

1. To compare overall survival in patients with platinum sensitive recurrent ovarian cancer with a positive AGO-score randomized to tumour debulking surgery followed by chemotherapy of physician's choice versus chemotherapy of physician's choice alone.

2. Quality of Life. To compare progression-free-survival in treatment groups. To analyze complications associated with surgery and perioperative mortality in patients with relapsed ovarian cancer in a multicenter setting. Exploratory analysis of surgical and treatment characteristics.

Summary of proposed study:

This is an open-label, prospective, randomized, international, multicentre phase III surgery trial following an international protocol developed in Germany. 408 patients (204/group) will be randomized to experimental or control treatment in a 1:1 ratio over a period of 30 months. All participants will be followed up until observation of 244 events, which is expected at 36 months after randomization of the last patient (i.e. 72 months after start of the trial). The UK is expected to recruit approximately 100 of the total patients.

Practical Arrangements:

The trial is an international trial organised by the AGO Study Group Ovarian Cancer and will be managed by the AGO Study Office, Wiesbaden and the Coordinating Centre for Clinical Studies (Koordinierungszentrum für Klinische Studien) Marburg, Germany. These offices will manage and oversee protocol development, patient randomisation, data management and development and maintenance of the Electronic Data Capture (EDC) system. The CRCTU will act as the national co-ordinating centre for the UK and so will initiate the sites, distribute relevant trial-related materials and act as the day-to-day contact for the trial. Data will be collected by ECRF and will be sent directly to the international co-ordinating centre for analysis. The grant application is to cover a full time Trial Coordinator (TC) for the first year to guide the applications through the regulatory channels and to set-up the UK sites. In the subsequent 2 years this drops to a half-time TC to maintain regulatory compliance. The post-recruitment phase will be funded from CRCTU core funds.

Trial Schema: