
***NRG GY019* A Randomized Phase III, Two-Arm Trial of
Paclitaxel/ Carboplatin/Maintenance Letrozole Versus
Letrozole Monotherapy in Patients with Stage II-IV, in
Primary Low-Grade Serous Carcinoma
of the Ovary or Peritoneum**

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Status: Protocol in Development

GCIG 5th OCCC conclusions on LGSOC:

1. Early stage: *surgery alone can be curative*

2. **Advanced stage:**

platinum/taxane or single agent platinum chemotherapy

no prospective controlled data to change this control arm

3. Recurrent disease:

platinum sensitive/platinum resistant

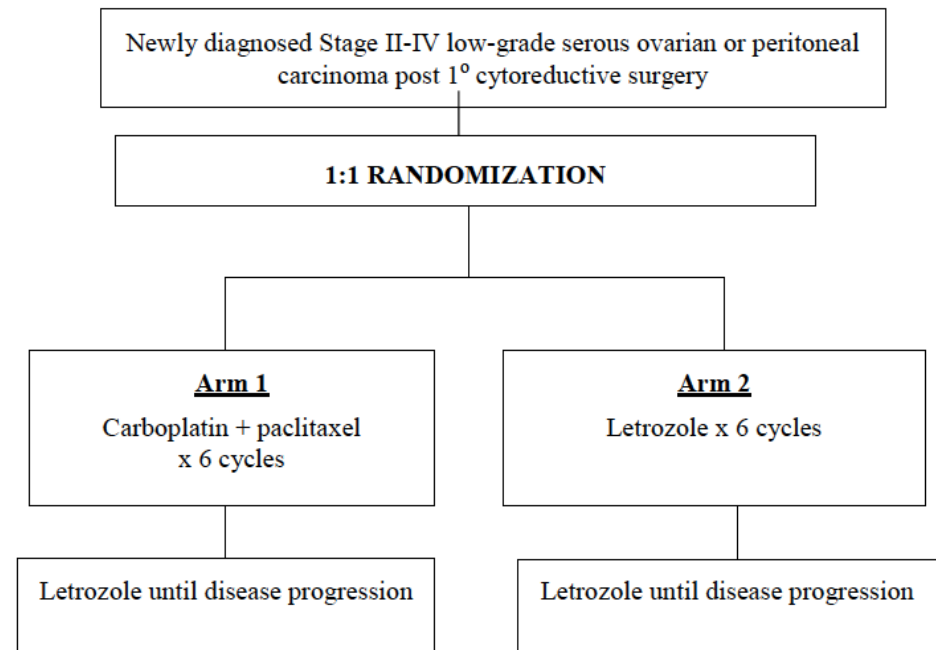
no prospective controlled data to drive change in this control arm

no prospective controlled data to support anti-hormone

approaches

Up Front Treatment of LGSOC

- **Newly diagnosed stage II-IV LGSOC or invasive micropapillary serous cancer (centrally confirmed pending funding)**
- **P53 review to rule out HGSOC**
- **Attempt at optimal cytoreduction**
- **Postmenopausal or undergone BSO**
- **ECOG 0-2**
- **Adequate end organ function**
- **No prior NACT, RT for this disease, no prior hormonal treatment**



Primary objective: PFS

International opportunities:

- Study requires international participation for success
- Letrozole is used as SoC in the US and is not provided for the study
- Real time v retrospective pathology, who, where, when pending
- Recommend participation via NCTN for fully rostered NCTN members (NRG Japan, KGOG, selected ANZGOG and EORTC sites, etc)
- Options for nonrostered sites include:
 - Parallel identical protocols with ongoing data merge via central organizing site with NCI clearance (1572/US DoS approval)
 - Parallel identical protocols with data merge prior to primary analysis
 - Further options may be available upon discussion.

NOTE: NCI has mandated that trial is activated prior to international participation.