Desktop II

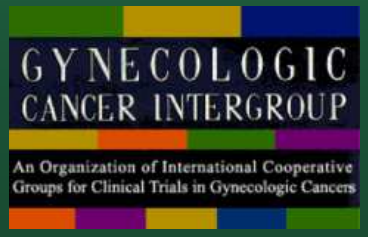
- 3 faktorer prediktiva för bra resultat av kirurgi vid recidiv ovarialcancer;

- <500 ml ascites
- ingen makroskopisk kvarlämnad tumör vid primär kirurgi
- bra allmän tillstånd

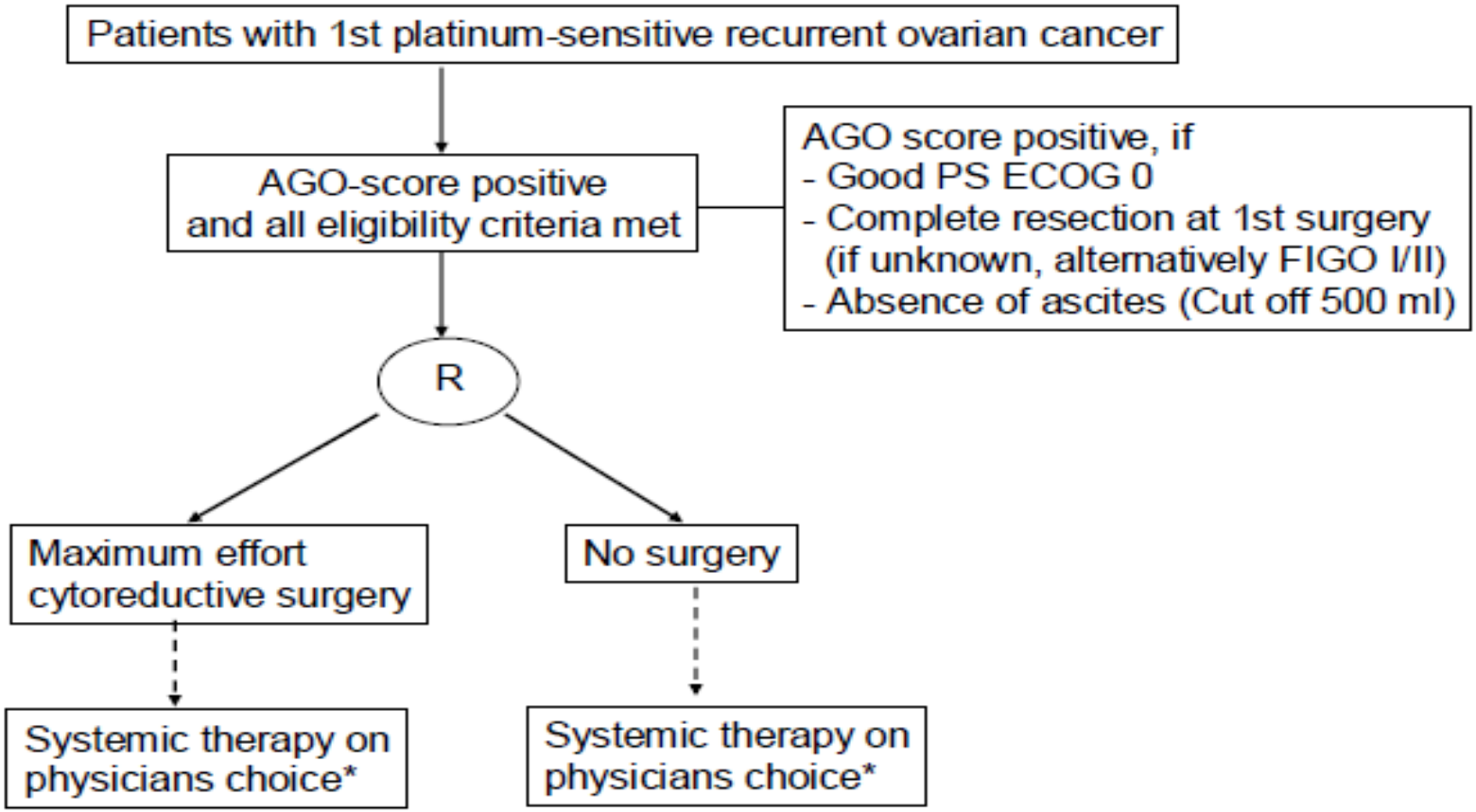
DESKTOP OVAR III

Prospectively randomized evaluation of cytoreductive surgery as adjunct preceding standard platinum-based chemotherapy in platinum-sensitive recurrent cancer of the ovary, fallopian tube, or peritoneum

AGO Study Group Ovarian Cancer (AGO-OVAR)



An open-label prospectively randomized phase III multicenter-trial



* Systemic therapy outside the study protocol, recommendation only

Eligible patients will be randomized after they have given informed consent. In patients randomized to surgery, surgery has to be performed within 6 weeks after randomization. In patients randomized to systemic therapy only, therapy has to be started within 6 weeks after randomization.

AGO-OVAR DESKTOP III

Primary objective:

- Overall survival

Secondary objectives:

- Progression-free survival
- Quality of Life
- Rate of complete resection as prognostic factor
- Complication rates of surgery
- Exploratory analysis of surgical characteristics and chemotherapy, prognostic factors

AGO-OVAR DESKTOP III

Inclusion criteria (1):

- Patients with 1st recurrence of platinum sensitive, invasive epithelial ovarian-, fallopian tube- or primary peritoneal cancer of any inital stage

- Progression-free interval of at least 6 months after end of last platinum based chemotherapy OR recurrence within 6 months or later after primary surgery if the patient has not received prior chemotherapy in patients with FIGO I.

AGO-OVAR DESKTOP III

Inclusion criteria (2):

(1) Performance status ECOG 0

(2) Complete resection at 1st surgery (if unknown FIGO I/II).

(3) Absence of ascites (cut off 500 ml)

Complete resection of the tumor seems possible (estimated by an experienced surgeon). Intra-abdominal disease has to be excluded by MRI/CT, if other surgical approaches for extra-abdominal recurrences only are planned

- Age > 18 years, signed and written informed consent

AGO-OVAR DESKTOP III

Statistics: HR 0.7 favouring surgery

Sample size: 408 patients/244 events

- Recruitment: 36 months

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- limited funding - participating groups have to pay local co

NCI-C

- **Randomized trial comparing radical hysterectomy and pelvic node dissection vs simple hysterectomy and pelvic node dissection in patients with low risk cervical cancer defined as lesions measuring less than 2cm with less than 50% stromal invasion**

- **An Intergroup trial of the National Cancer Institute of Canada (NCI-C)**
- **PI: Marie Plante**

- **Trial design**
- This is a 1:1 multicenter randomized trial with radical hysterectomy plus pelvic node dissection as the control arm, and simple hysterectomy plus node dissection as the experimental arm (750 patients in each arm).

- The primary study endpoint will be the 2-year pelvic recurrence rate

NCI-C

- **Primary Objective**
  Evaluate whether the difference between local recurrence rates for patients treated with radical hysterectomy and nodes and those undergoing simple hysterectomy and nodes is greater than 2%.

- **Secondary Objectives**
  rates of treatment-related toxicity
  extrapelvic relapse
  survival
  rates of sentinel node detection and parametrial margins
  pelvic nodes involvement
  quality of life, including a sexuality

Option: **NE**twork **ST**udy in **E**ndometrial **C**ancer *under the ENGOT umbrella and in cooperation with the Mayo clinic.*

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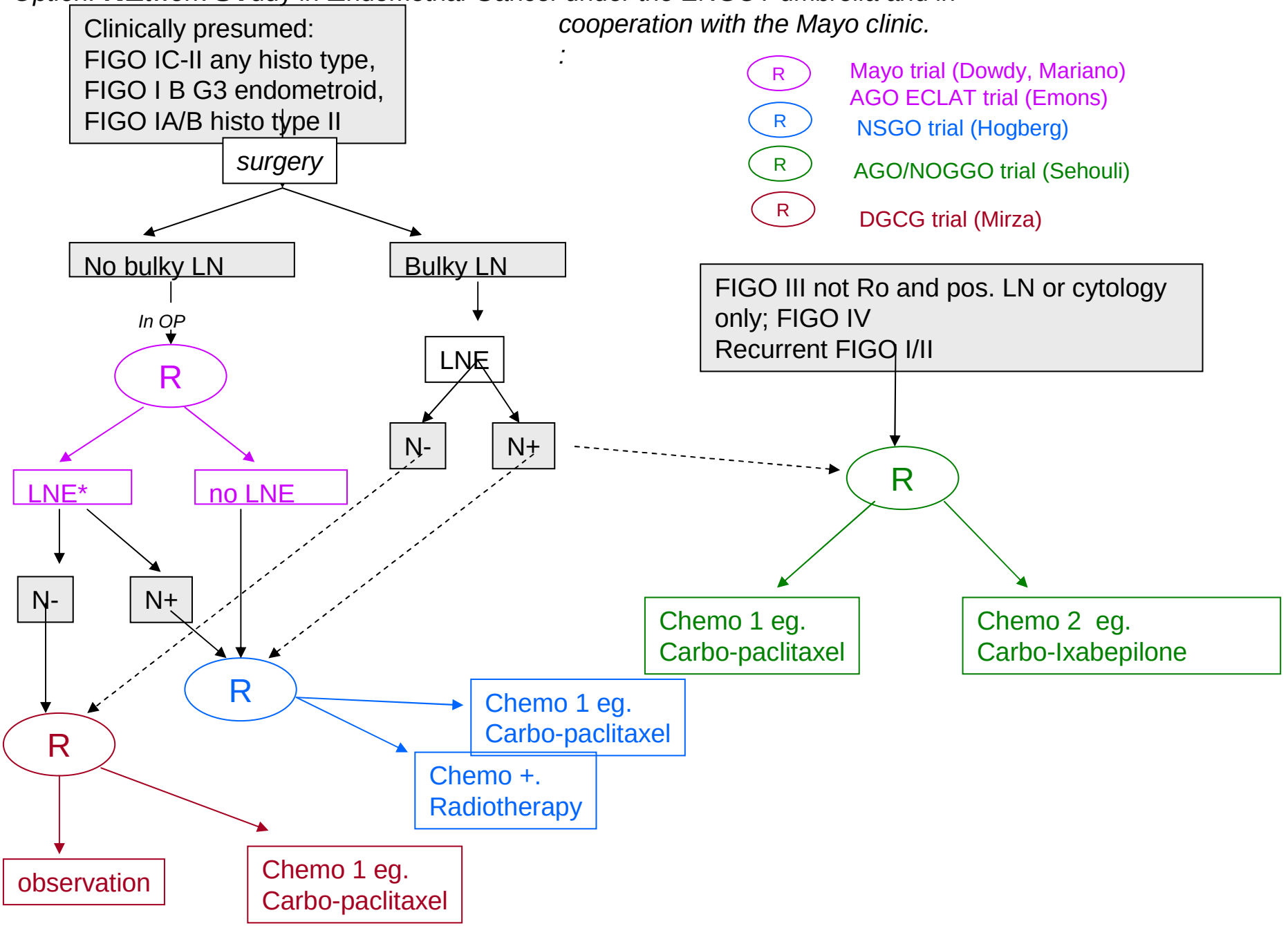

**LNE = Pelvic + para-aortic; Definitions according to LION or Definitions according to Mayo (No.)*

ENGOT-EN2

- Fas III studie av postoperativ chemo (taxol/paraplatin 6 kurer) vs ingen adjuvant behandling för lymfkörtelneg stad I-II

- Stad I grad 3 endo adeno
- Stad II endom adeno
- Stad I och II typ 2 histologi (klarcell, serös, skivepitel)

ENGOT-EN2

- Operation TAH+BSO (el RH)+pelvin lymfkörtelutrymning
- Lymfkörtelutrymning; minimum 12 pelvina körtlar, paraortalt fritt val
- Omentektomi typ II histopatologi
- Vaginal brachy rekommenderas ej men tillåts i båda grupperna
- WHO, performance status 0-2

ENGOT-EN2

- Primärt mål OS

- Sekundära mål;
- PFS
- Toxicitet
- Komplikationer
- QoL
- Recidiv (lokalt och fjärrmet)