



Endometrial Cancer Committee Minutes Milan September 8, 2011



David Miller, Ketta Lorusso



Endometrial Cancer Committee Agenda

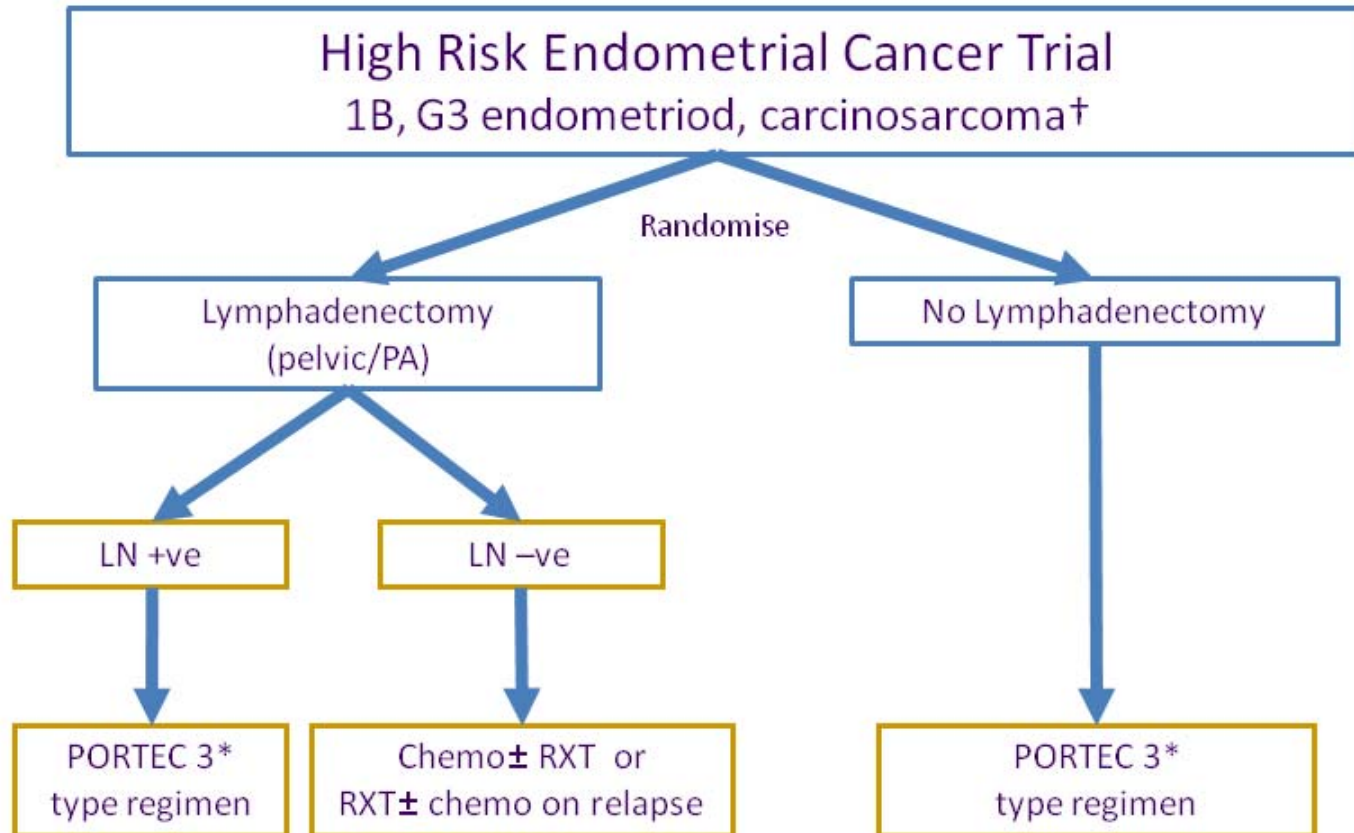
Milan September 8, 2011

ENDOMETRIAL STAGING

2) PLASTEK

“Perfect” Lymphadenectomy /
Adjuvant Study in the Treatment of
Endometrial Cancer

PLASTE_C (“Perfect” Lymphadenectomy/Adjuvant Study in the Treatment of Endometrial Cancer)





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ENDOMETRIAL STAGING

3) KGOG 2015

Validation of low-risk criteria for lymph node metastasis in endometrial cancer: multicenter, prospective observational cohort study

KGOG2015

**Preoperative Prediction of
Low-risk Group for Lymph Node
Metastasis
in Endometrial Cancer**

Study chair: Sokbom Kang

Study co-chair: Jae Weon Kim

Uterine Cancer Committee of

Korean Gynecologic Oncology Group

KGOG-2015

Eligibility criteria

- **Patient eligibility**
 - Informed consent
 - Must have histologically confirmed endometrial cancer
 - Must have undergone MRI and CA125
 - Must be candidates of surgical staging including lymphadenectomy
- **Exclusion criteria**
 - Inadequate preoperative biopsy
 - Sarcomatous or squamous cell type histology

KGOG-2015

Study scheme

Patient screening

- Review of preoperative data (MRI, CA125, Biopsy)
- Risk classification



Review of surgical staging data

- Review of surgical staging record
- Sequential testing¹ for early stopping rule



Final analysis

- Estimate false negative rate at the assumed prevalence of 10%



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ENDOMETRIAL ADJUVANT

1) ENGOT-EN2-DGCG

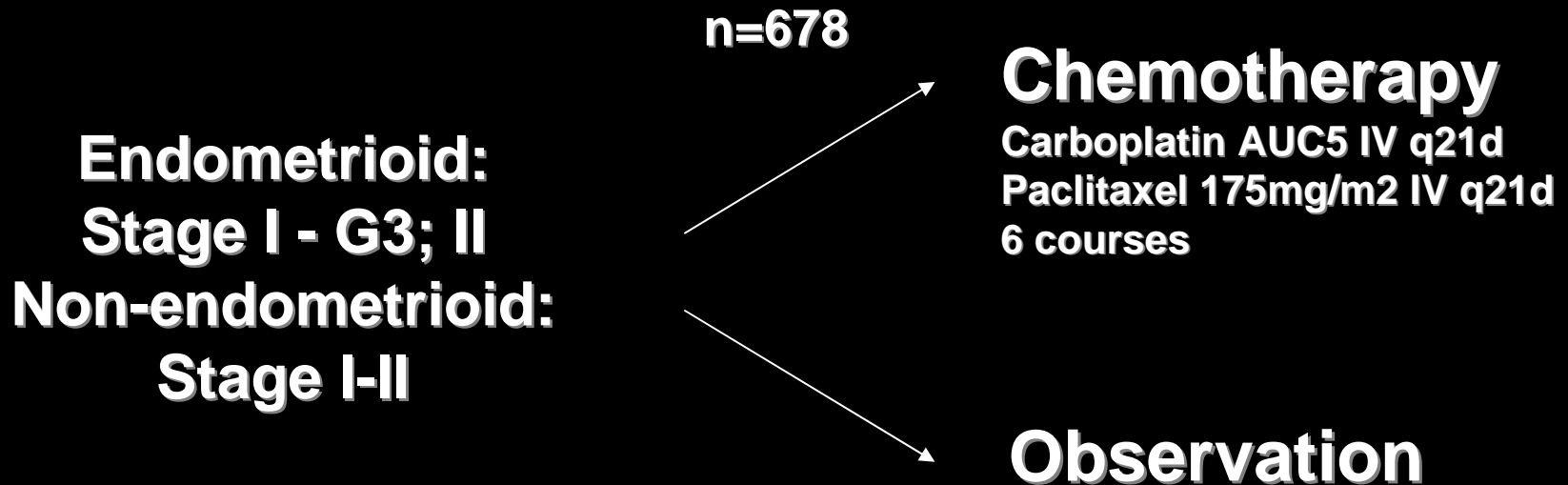
A phase III trial of postoperative chemotherapy or no further treatment for patients with node negative stage I-II intermediate or high risk endometrial cancer:

Design

Node-negative patients; 1:1 randomization

Stratifications

- 1: endometrioid vs non-endometrioid
- 2: stage 1 vs. stage 2 disease
- 3: para-aortic (≥ 10) and pelvic (≥ 20) LNE vs. lesser LNE
- 4: Brachytherapy planned yes/no



Participating Groups

DGCG (Lead Group)

NSGO

EORTC

AGO (Germany)

NOGGO (Germany)

AGO (Austria)

BGOG (Belgium)

MaNGO (Italy)

MAYO Clinic (USA)

JGOG (Japan)



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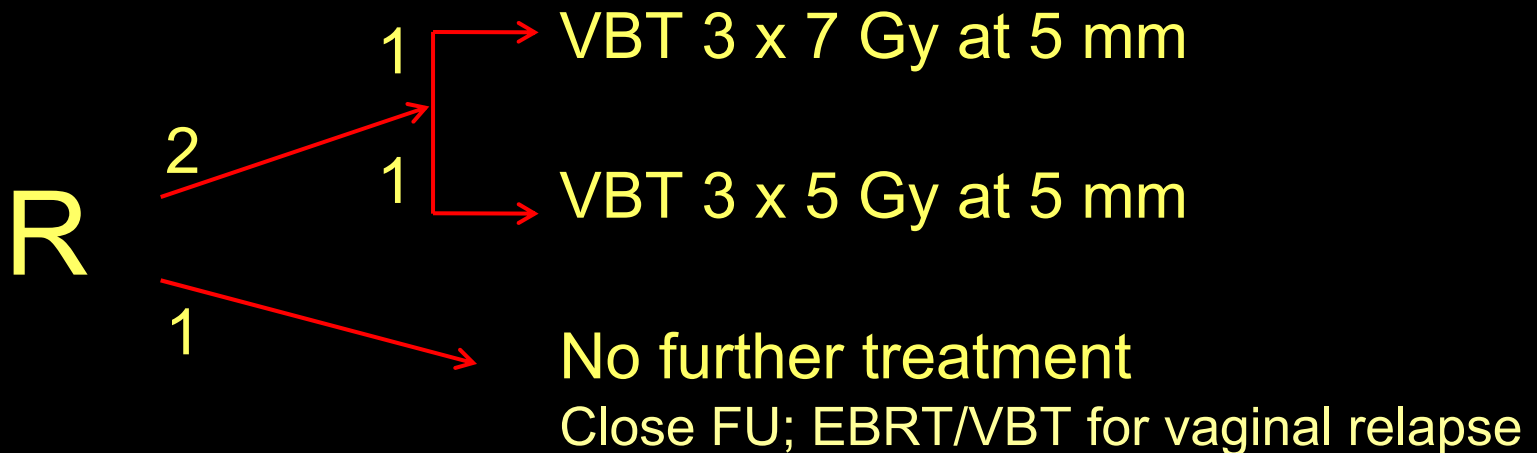
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ENDOMETRIAL ADJUVANT

PORTEC 4: Randomized trial of vaginal brachytherapy vs observation for high-intermediate risk endometrial carcinoma

PORTEC-4 design

- *HIR endometrial carcinoma*
- *21 Gy in 3 fractions vs 15 Gy in 3 fractions*
- *Vaginal brachytherapy vs no further treatment*





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UTERINE LEIOMYOSARCOMA

1) GOG UC1009

A Randomized Phase III trial of Gemcitabine plus Docetaxel followed by Doxorubicin vs Observation for early stage High Grade Uterine Leiomyosarcoma

EORTC

SCHEMA

Enroll patients with
1) High grade uterine LMS
2) FIGO 2009 Stage I (uterus
+/- cervix)
3) Hysterectomy +/-BSO

RA
ND
OMI
zE

Gemcitabine 900 mg/m² IV days 1 and 8
Docetaxel 75 mg/m² IV day 8
GCSF 5 micrograms/kg days 9-15 or
Neulasta 6 mg day 9 or 10
Every 21 days for 4 cycles
CT/MRI imaging to confirm disease-free
Doxorubicin 60 mg/m² IV every 21 days
for 4 cycles (GCSF is optional)

Observation

CT/MRI
imaging
every 4
months for 3
years, then
every 6
months for 2
years.



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TROPHOBLASTIC NEOPLASIA

1) GOG UC 1005

A sequential phase II/III randomized trial comparing 3 widely used regimens for the management of low risk Gestational Trophoblastic Neoplasia (John Tidy: john.tidy@sth.nhs.uk). Interested groups: AGO Aust., JGOG, MITO

GOG-0275: A PHASE III RANDOMIZED TRIAL OF PULSE ACTINOMYCIN-D VERSUS MULTI-DAY METHOTREXATE FOR THE TREATMENT OF LOW-RISK GESTATIONAL TROPHOBLASTIC NEOPLASIA



Eligible patients:

Low-risk persistent GTN

FIGO Stage I, II, III

WHO Score 0-6

R
A
N
D
O
M
I
Z
E

Arm Regimen 1: Patients will receive IV pulse actinomycin-D ($1.25\text{mg}/\text{m}^2$) every 14 days. (2mg max dose)

Arm Regimen 2: Patients will receive their institutional preference of either:

- IV methotrexate ($0.4\text{ mg}/\text{kg}$) daily for 5 days every 14 days. (25mg max daily dose)

OR

- IM methotrexate (50mg) on Days 1, 3, 5, 7 (4 doses per cycle) with folinic acid (15mg) on Days 2, 4, 6, 8. Repeat every 14 days.