Princess Margaret Consortium

GYNECOLOGIC CANCER INTERGROUP
An Organization of International Cooperative Groups for Clinical Trials in Gynecologic Cancers

DUTCH GOG
Dutch Gynaecological Oncology Group

NETHERLANDS CANCER INSTITUTE
ANTONI VAN LEEUWENHOEK

Stage IB1 (2-4 cm) Cervical cancer treated with Neoadjuvant chemotherapy followed by fertility Sparing Surgery (CONTESSA)

Dre Marie Plante

Neo-Adjuvant Chemotherapy and Conservative Surgery in Cervical Cancer to Preserve Fertility (NEOCON-F)

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CONTESSA / NEOCON-F

CONTESSA

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Specific Hypothesis

- Neoadjuvant chemotherapy (NACT) in node-negative women with stage IB1 (2-4 cm) cervical cancer will enable fertility preserving surgery without compromising oncologic outcome in good chemo-responders

Primary Objective #1

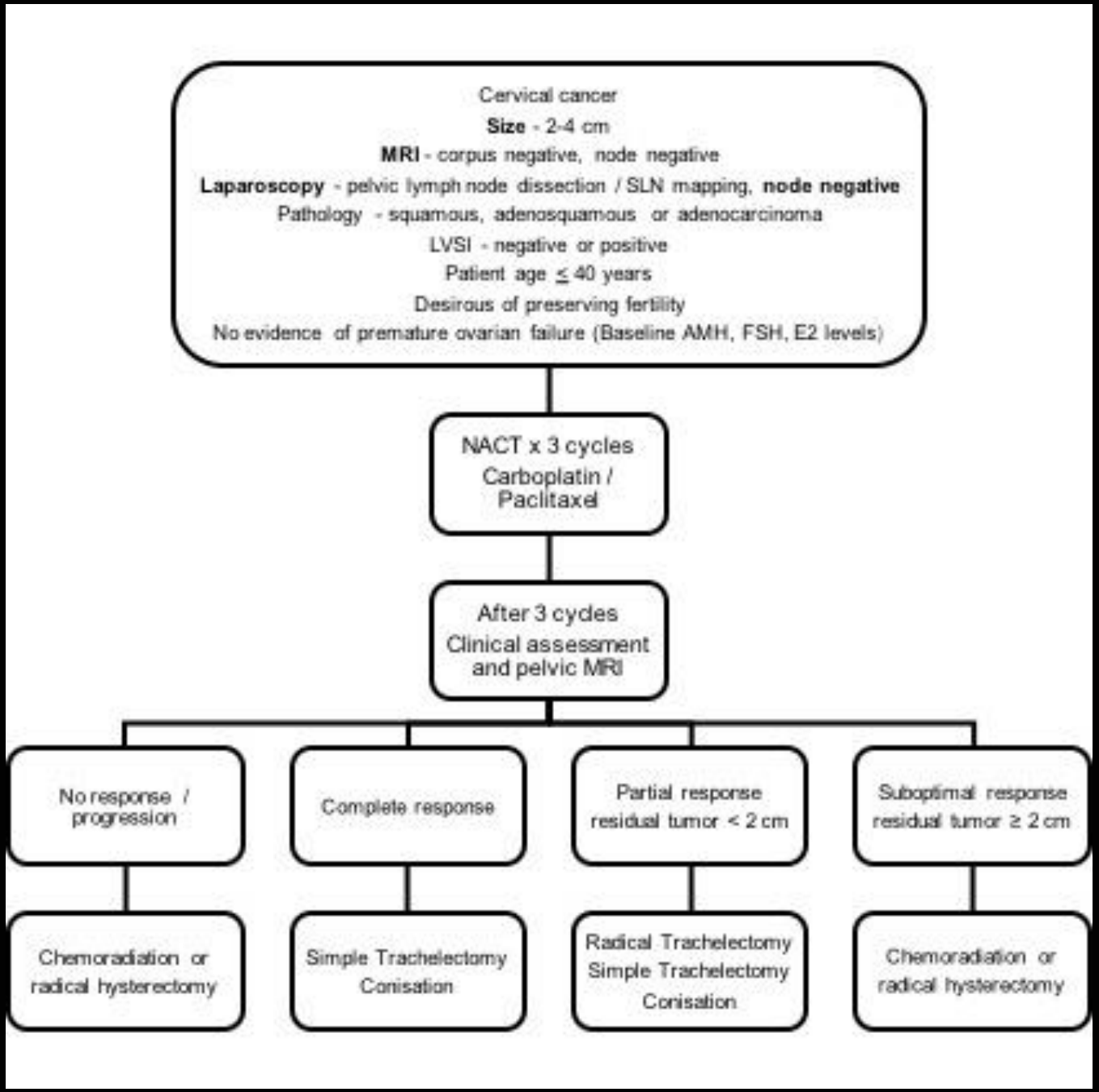
- To evaluate the safety of NACT in women with node negative, stage IB1 cervical cancer with lesions measuring 2-4 cm

Primary Objective #2

- To evaluate the **rate of fertility preserving surgery (FPS)** following neoadjuvant chemotherapy (NACT)

Secondary Objectives

- Chemotherapy related adverse events / safety
- Surgical complication rate of FPS
- Requirement for adjuvant radiation therapy (trimodality treatment)
- Requirement for definitive hysterectomy
- Quality of Life
- Ovarian function, rates of pregnancy and obstetrical outcomes


Cervical cancer
Size - 2-4 cm
MRI - corpus negative, node negative
Laparoscopy - pelvic lymph node dissection / SLN mapping, node negative
Pathology - squamous, adenosquamous or adenocarcinoma
LVSI - negative or positive
Patient age ≤ 40 years
Desirous of preserving fertility
No evidence of premature ovarian failure (Baseline AMH, FSH, E2 levels)
NACT x 3 cycles
Carboplatin / Paclitaxel
After 3 cycles
Clinical assessment and pelvic MRI
No response / progression
Complete response
Partial response residual tumor < 2 cm
Suboptimal response residual tumor ≥ 2 cm
Chemoradiation or radical hysterectomy
Simple Trachelectomy Conisation
Radical Trachelectomy Simple Trachelectomy Conisation
Chemoradiation or radical hysterectomy

Primary endpoints

- Recurrence rate/PFS at 3 years (#1)
- Intact functional uterus following NACT and FPS (#2)

Secondary endpoints

- Response rate to NACT
- Adverse events and safety
- Surgical complication rate
- Rates of definitive hysterectomy
- Requirement for adjuvant radiation therapy (trimodality treatment)
- QOL: EORTC QLQ C30 and QLQ CX 24
- Disease Outcomes: PFS at 2 years
- Ovarian function (FSH, estradiol, AMH)
- Pregnancy rates and obstetrical outcomes

Statistical analysis

- Phase II study
- Prospective, multi-center, international trial

Statistics : PRELIMINARY

- To be finalized

Translational research

- Assessment of **tumor response**
  - Circulating tumor DNA (ctDNA)
  - Serial blood sample collection
    - Baseline
    - Chemotherapy cycle 2
    - Surgery
    - 3-month follow-up visit

Summary

- Feasable study
- Count on international collaboration
- Will provide solid data as to the safety of this approach and standardize the procedure