Studie informatie in één oogopslag

Naam van de studie
FIGO 2018 stage IB2 (≥2cm - <4 cm) Cervical Cancer Treated with Neoadjuvant Chemotherapy Followed by Fertility Sparing Surgery (CoNteSSa) / Neo-Adjuvant Chemotherapy and Conservative Surgery in Cervical Cancer to Preserve Fertility (NeoCon-F)
Inclusie criteria
3.1.1 Patients must have histologically confirmed invasive cervical cancer with adenocarcinoma, adenosquamous or squamous histology and FIGO 2018 IB2 measuring >2cm to <4cm by radiological imaging (MRI). Lymphovascular space invasion (LVSI) is allowed. **NOTE: Patients must have undergone complete lymph node dissection with or without SLN mapping prior to study entry (laparoscopic complete lymph node dissection) and be pathologically node-negative. SLN mapping procedure (Appendix A)** **3.1.2 Patients must be ≥18 years of age, and < 40 years of age** **3.1.3 Patients must be premenopausal and wish to preserve fertility** **3.1.4 At time of registration, patient may not have had any prior therapy to treat their cancer lesion, patients with diagnostic cone or LEEP are allowed** **3.1.5 Eastern Cooperative Group (ECOG) performance status ≤ 2 (Karnofsky ≥60%, see Appendix C).** **3.1.6 Within 7 days of the proposed start of treatment, patients must have normal organ and marrow function as defined below:** **Haemoglobin > 100 g/L** **Leukocytes (WBC) 3.0x109/L** **absolute neutrophil count ≥1.5x109/L** **platelets ≥100x109/L** **total bilirubin within normal institutional limits** **AST(SGOT)/ALT(SGPT) ≤2.5 × institutional upper limit of normal** **creatinine within normal institutional limits** **3.1.7 No evidence of active uncontrolled infection (patients on antibiotics are eligible).** **3.1.8 Patient must have disease that is measurable per RECIST 1.1.** **3.1.9 Ability to understand and willing to sign a written informed consent document.** **3.1.10 Patients must agree to use effective contraceptive methods prior to study entry, during study participation, and for at least one year after the FSS procedure. A serum pregnancy test within 72 hours prior to study registration is required.** **Highly effective contraception methods include:** **• Total abstinence when this is in line with the preferred and usual lifestyle of the subject. Periodic abstinence (e.g., calendar, ovulation, symptothermal, post-ovulation methods) and withdrawal are not acceptable methods of contraception** **• Combination of any two of the following (a+b or a+c, or b+c):**

a) Use of oral, injected or implanted hormonal methods of contraception or other forms of hormonal contraception that have comparable efficacy (failure rate <1%), for example hormone vaginal ring or transdermal hormone contraception
b) Placement of an intrauterine device (IUD) or intrauterine system (IUS)
c) Barrier methods of contraception: condom or occlusive cap (diaphragm or cervical/vault caps) with spermicidal foam/gel/film/cream/vaginal suppository

In case of use of oral contraception women should have been stable on the same pill for a minimum of 3 months before taking study treatment.
Part 2 – Eligibility Criteria for Fertility Sparing Surgery (FSS)
3.1.11 Completed 3 cycles of neoadjuvant chemotherapy and achieved a complete response (CR) or partial response (PR) with reduction of the lesion to <2 cm on physical examination and MRI.

3.2 Exclusion Criteria
Part 1 – Exclusion Criteria for Neoadjuvant Chemotherapy
3.2.1 Patients who have had chemotherapy or radiotherapy or surgery for their cancer. Patients with diagnostic cone or LEEP are allowed

3.2.2 Patients who are receiving any other investigational agents.

3.2.3 Patients with other cancers requiring ongoing treatment. Patients with malignancies unrelated to their cervical cancer can be included if they have not required treatment for 2 years. Patient with baso cellular skin cancer are allowed.

3.2.4 Patients with known / evidence of brain metastases are excluded from participation in this clinical trial.

3.2.5 History of allergic reactions attributed to compounds of similar chemical or biologic composition to paclitaxel, carboplatin, or cisplatin or other agents used in study.

3.2.6 Uncontrolled inter-current illness including, but not limited to, ongoing or active infection, symptomatic congestive heart failure, unstable angina pectoris, cardiac arrhythmia, or psychiatric illness/social situations that would limit compliance with study requirements.

3.2.7 Patients who are pregnant or breastfeeding

3.2.8 Any other condition that would, in the Investigator's judgment, contraindicate the patient's participation in the clinical study due to safety concerns or compliance with clinical study procedures, e.g., infection/inflammation, intestinal obstruction, unable to swallow medication, social/ psychological issues.

Part 2 – Exclusion Criteria for Fertility Sparing Surgery
3.2.9 Patient unable to complete 3 cycles of neoadjuvant chemotherapy

3.2.10 Suboptimal response to neoadjuvant chemotherapy according to local investigator

3.2.11 Residual lesion > 2cm or disease progression while on chemotherapy

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Randomisatie

NvT

Flowchart

Zie bijlage, lukt niet om in te plakken

Aanvullende onderzoeken bij randomisatie of tijdens de studie
- MRI bij studie screening, als respons evaluatie NACT en exit MRI bij 3 jaar follow-up **- hrHPV meting in serum en hrHPV+methyleringsmarkers in uitsrijken bij start studie, eenmalig tijdens chemotherapie en bij follow-up**
Follow up schema
Jaar 1 en 2 a 3 maanden **Jaar 3 a 6 maanden**
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Datum van invullen
15-12-20