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Clinical Trial Protocol

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A phase II study of induction PD-1 blockade (nivolumab) in patients with surgically completely resectable mismatch repair deficient endometrial cancer (NIVEC)

OPEN ACCESS

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ABSTRACT

Background: Mismatch repair deficient (MMRd) tumors are known to be highly immunogenic and of great interest for immune checkpoint inhibitor. However, there is no data about the complete response (CR) rate of programmed cell death protein 1 (PD-1) blockade and surgery in subjects with MMRd surgically resectable endometrial cancer. In this regard, we suggest a window of opportunity study of induction PD-1 blockade (nivolumab) in patients with surgically resectable MMRd endometrial cancer.
Methods: This is a multicenter, single-arm phase II trial. A total of 30 surgically resectable MMRd endometrial cancer patients will be enrolled. Inclusion criteria include clinical stage I–IIIC2, tumor specimen that demonstrates MMRd by immunohistochemistry or microsatellite instability. Exclusion criteria include multiple primary cancers, residual adverse effects of prior therapy or effects of surgery. Patients are treated with nivolumab 480 mg intravenously every 4 weeks up to 6 months followed by standard surgery and/or adjuvant treatment. The primary endpoint of the study is clinical CR rate or pathological CR rate after treatment of nivolumab. Secondary endpoints include objective response rate, progression-free survival, overall survival, and adverse events. Correlative studies include genomic characterization of tumors, assessment of immune infiltration of tumor microenvironment, and serial circulating cell-free DNA and immune biomarkers.

Trial Registration: ClinicalTrials.gov Identifier: NCT05795244

Keywords: Endometrial Cancer; PD-L1 Inhibitor; Mismatch Repair Deficiency

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Conflict of Interest
No potential conflict of interest relevant to this article was reported.

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Synopsis
Mismatch repair deficiency (MMRd) endometrial cancers are known to be highly immunogenic and of great interest for immune checkpoint inhibitor. Here, we describe the protocol of the multicenter, single-arm phase 2 NIVEC study investigating induction nivolumab in patients with surgically resectable MMRd endometrial cancer.

INTRODUCTION

Endometrial cancer is the second most common type of gynecologic cancer and the sixth most common cancer in women globally [1,2]. Standard of care for resectable endometrial cancer is surgery and/or adjuvant treatment. Even after treatment is completed, these patients have a risk of local and systemic disease recurrence. The expected disease recurrence rate for stage I–III endometrial cancer is between 6%–38% despite treatment [3].
The combination of adjuvant chemotherapy and radiotherapy provides local tumor control, but incidence of distant metastasis approaches 22%, heralding subsequent death [4].

Mismatch repair deficient (MMRd) or microsatellite instability-high (MSI-H) tumors account for approximately 20%–30% of endometrial cancer [5]. MMRd/MSI-H tumors are associated with high programmed cell death protein 1 (PD-1) and programmed death-ligand 1 (PD-L1) expression, indicating a higher likelihood of response to anti-PD-1 and anti-PD-L1 inhibitors [6]. Immune checkpoint inhibitor (ICI) has been shown to be highly effective for patients with MMRd recurrent endometrial cancer, with objective response rates (ORRs) of 43 to 57%, clinically significant durability of response, and prolonged progression-free survival (PFS) [7-9].

ICIs as neoadjuvant chemotherapy (NAC) has demonstrated potential in enhancing pathological complete responses (pCRs) in different types of cancer. The incorporation of nivolumab in neoadjuvant setting showed high major pathologic response (MPR) in resectable non–small-cell lung cancer (MPR 38%) [10]. In the NICHE [11] and NICHE-2 [12] study, patients with MMRd/MSI-H colorectal cancer who received ipilimumab and nivolumab before surgery demonstrated high response rates and pCR. Furthermore, Cercek et al. [13] demonstrates that PD-1 blockade is highly effective in achieving a clinical complete response (CR) (100%) in patients with MMRd, locally advanced rectal cancer. On the basis of these results, we hypothesized that single agent PD-1 blockade might have the benefit of increasing response rates in MMRd, surgically resectable endometrial cancer.

Therefore, this NIVEC study (ClinicalTrials.gov, NCT05795244) is conducted to investigate the CR rate of neoadjuvant treatment of nivolumab and surgery in subjects with MMRd surgically resectable endometrial cancer.

MATERIALS AND METHODS

1. Objectives

Eligible criteria

To be eligible for the trial, patients must meet the following criteria:

1) Explicit and voluntary consent to participation in the trial obtained by signing and

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dating an informed consent form that clearly and completely describes the purpose, potential risks, and other important issues related to the study.
2) Sex: Female.
3) Age (at the time of informed consent): 20 years and older.
4) Subjects with histologically-or cytologically-confirmed endometrial cancer or carcinosarcoma (mixed Müllerian tumor).
5) Clinical stage: Stage I–IIIC2 and surgically completely resectable.
6) No evidence of distant metastases.
7) MMRd or MSI-H subtype (defined by either deficient/loss expression of mismatch repair [MMR] proteins MLH1, PMS2, MSH2, MSH6 or MSI-H by polymerase chain reaction assay for 5 microsatellite markers).
8) Eastern Cooperative Oncology Group Performance Status Score 0 or 1.
9) Patients with a life expectancy of at least 3 months.
10) Patients whose latest laboratory data meet the below criteria within 7 days before first dose. If the date of the laboratory tests at the time of enrollment is not within 7 days before the first dose of the investigational product, testing must be repeated within 7 days before the first dose of the investigational product, and these latest laboratory tests must meet the following criteria. Of note, laboratory data will not be valid if the patient has received a granulocyte colony-stimulating factor or blood transfusion within 14 days before testing.
    - White blood cells ≥2,000/mm^3 and neutrophils ≥1,500/mm^3
    - Platelets ≥100,000/mm^3
    - Hemoglobin ≥9.0 g/dL
    - Aspartate aminotransferase (glutamic oxaloacetic transaminase) and alanine aminotransferase (glutamic pyruvic transaminase) ≤3.0-fold the upper limit of normal (ULN) of the study site (or ≤5.0-fold the ULN of the study site in patients with liver metastases)
    - Total bilirubin ≤1.5-fold the ULN of the study site
    - Creatinine ≤1.5-fold the ULN of the study site or creatinine clearance (either the measured or estimated value using the Cockcroft-Gault equation) >45 mL/min
11) Women of childbearing potential (including women with chemical menopause or no menstruation for other medical reasons) #1 must agree to use contraception #2 from the time of informed consent until 5 months or more after the last dose of the investigational product. Also, women must agree not to breastfeed from the time of informed consent until 5 months or more after the last dose of the investigational product.

Exclusion criteria

Patients who meet any of the following criteria are not eligible for the study.

1) Patients with multiple primary cancers (except for cancer that are not expected to affect the clinical trial outcomes, such as completely resected basal cell carcinoma, stage I squamous cell carcinoma, carcinoma in situ, intramucosal carcinoma, or superficial bladder cancer, or any other cancer that has not recurred for at least 3 years).
Other exceptions may apply and discussion between the investigator and the sponsor may be necessary.
2) Patients with residual adverse effects of prior therapy or effects of surgery that would affect the safety evaluation of the investigational product in the opinion of the investigator or sub-investigator.
3) Patients with current or past history of severe hypersensitivity to any other antibody products.

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4) Patients with concurrent autoimmune disease or history of chronic or recurrent autoimmune disease.
5) Patients with a current or past history of interstitial lung disease or pulmonary fibrosis diagnosed based on imaging or clinical findings. Patients with radiation pneumonitis may be randomized if the radiation pneumonitis has been confirmed as stable (beyond acute phase) without any concerns about recurrence.
6) Patients with concurrent diverticulitis or symptomatic gastrointestinal ulcerative disease.
7) Patients with pericardial fluid, pleural effusion, or ascites requiring treatment.
8) Patients with uncontrollable, tumor-related pain.
9) Patients who have experienced a transient ischemic attack, cerebrovascular accident, thrombosis, or thromboembolism (pulmonary arterial embolism or deep vein thrombosis) within 180 days before randomization.
10) Patients with a history of uncontrollable or significant cardiovascular disease meeting any of the following criteria:
    - Myocardial infarction within 180 days before randomization
    - Uncontrollable angina pectoris within 180 days before randomization
    - New York Heart Association Class III or IV congestive heart failure
    - Uncontrollable hypertension despite appropriate treatment (e.g., systolic blood pressure ≥150 mmHg or diastolic blood pressure ≥90 mmHg lasting 24 hours or more)
    - Arrhythmia requiring treatment
11) Patients receiving or requiring anticoagulant therapy for a disease. Patients receiving antiplatelet therapy including low-dose aspirin may be enrolled.
12) Patients with uncontrollable diabetes mellitus.
13) Patients with systemic infections requiring treatment.
14) Patients who have received systemic corticosteroids (except for temporary use, e.g., for examination or prophylaxis of allergic reactions) or immunosuppressants within 28 days before randomization.
15) Patients who have received antineoplastic drugs (e.g., chemotherapy agents, molecular-targeted therapy agents, or immunotherapy agents) within 28 days before randomization.
16) Patients who have undergone surgical adhesion of the pleura or pericardium within 28 days before randomization.
17) Patients who underwent major surgery within 4 weeks or minor surgery within 7 days prior to administration of the first investigational drug. Subjects should have adequately recovered from toxicity or complications from the intervention prior to initiation of study drug administration. Subjects planning major surgery during the treatment period should be excluded from the study (however, 2 weeks for video-assisted thoracoscopic or open-and-closed surgeries).
    Note) Dilation and curettage under general anesthesia for diagnostic purposes is not applicable to the above, and the subject can be enrolled when the investigator judged that the patient has adequately recovered from the complications caused by the intervention.
18) Patients who have received radiotherapy within 28 days before randomization, or radiotherapy to bone metastases within 14 days before randomization.
19) Patients who have received any radiopharmaceuticals (except for examination or diagnostic use of radiopharmaceuticals) within 56 days before randomization.
20) Patients with a positive test result for any of the following: human immunodeficiency virus (HIV)-1 antibody, HIV-2 antibody, hepatitis B surface antigen (HBsAg), or hepatitis C virus antibody. Subjects who are HBsAg positive can participate in the study if their hepatitis B virus-DNA level is below the institutional lower limit of detection.
21) Women who are pregnant or breastfeeding, or possibly pregnant.

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22) Patients who have received any other unapproved drug (e.g., investigational use of drugs, unapproved combined formulations, or unapproved dosage forms) within 28 days before randomization.
23) Patients who have previously received Nivolumab, anti-PD-1 antibody, anti-PD-L1 antibody, anti-PD-L2 antibody, anti-CD137 antibody, anti-cytotoxic T-lymphocyte associated protein 4 antibody or other therapeutic antibodies or pharmacotherapies for regulation of T-cells.
24) Patients judged to be incapable of providing consent for reasons such as concurrent dementia.
25) Other patients judged by the investigator or sub-investigator to be inappropriate as subjects of this study.
26) Patient with current or past history of hypersensitivity to nivolumab.
27) Women of childbearing potential who has a positive urine pregnancy test within 72 hours prior to allocation. If the urine test is positive or cannot be confirmed as negative, a serum pregnancy test will be required.

2. Trial design

This is a multicenter, non-randomized, open-label, a phase II study is led by the Department of Gynecologic Oncology, Women's Life Medical Science, Yonsei University College of Medicine. Patients will be enrolled at 7 South Korea sites (Samsung Medical Center, Asan Medical Center, Korea University College of Medicine, National Cancer Center, Ewha Womans University College of Medicine, and Kyung Hee University Hospital at Gangdong).

Patients will be given nivolumab at a dose of 480 mg/intravenously every 4 weeks. They will be assessed for response at 12 weeks and every 3 months or if they develop clinical symptoms of progression. Following completion of 6 months of treatment (6 times, 4-week cycles) with nivolumab patients will receive surgery and/or adjuvant treatment per standard institutional guidelines. In adjuvant treatment, chemotherapy agent and radiation will be administered in accordance with local guidelines, and it is recommended to be treated according to National Comprehensive Cancer Network, European Society for Medical Oncology, and Korean Society of Gynecology Oncology guidelines (**Fig. 1**).

3. Primary endpoints

The primary endpoint is clinical CR rate or pathological CR rate after treatment of nivolumab in subjects with MMRd surgically resectable endometrial cancer. Response rate is evaluated by endometrial biopsies and imaging. Endometrial biopsies are obtained by hysteroscopy or dilatation and curettage. Clinical CR was defined as the absence of residual disease on endometrial biopsy and imaging test following completion of nivolumab in patients who did not undergo surgery. Pathological CR was defined as the absence of residual disease on the histologic examination in patients who undergo surgery. Additional details are provided in the protocol (**Data S1**).

4. Secondary endpoints

The secondary endpoints are the efficacy of nivolumab by assessment of the ORR, the PFS, overall survival (OS).

5. Exploratory endpoints

The exploratory objectives are the identification of biomarkers that may be indicative of clinical response/resistance, safety, and/or the mechanism of action of nivolumab.

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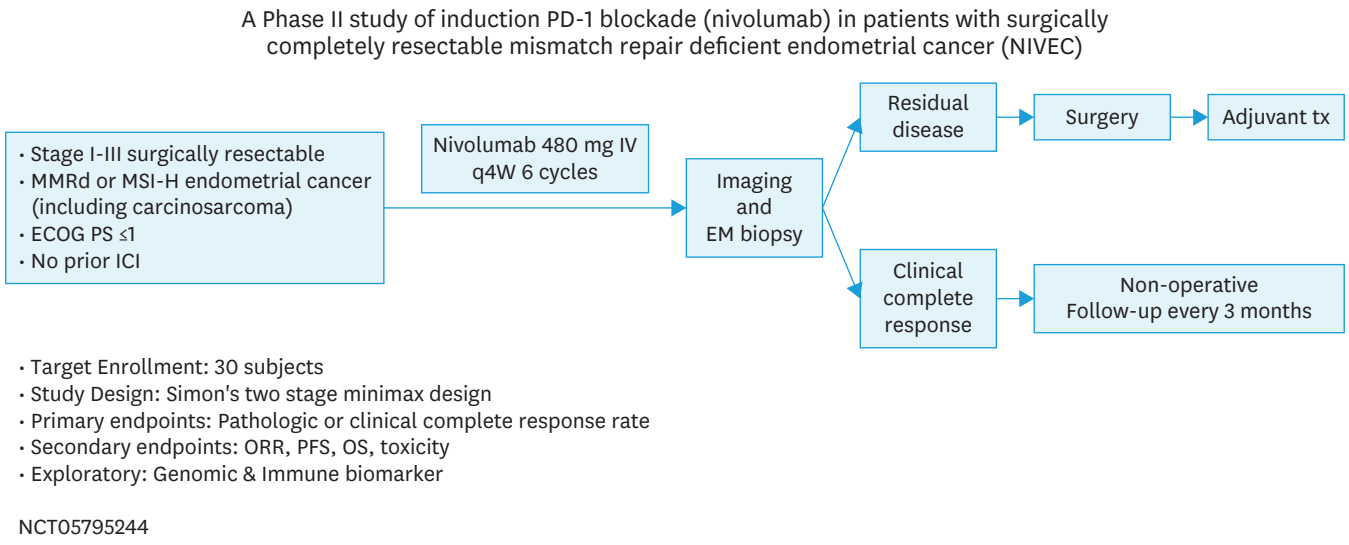

Fig. 1. Study schema.
ECOG, Eastern Cooperative Oncology Group; EM, endometrium; ICI, immune checkpoint inhibitor; IV, intravenously; MMRd, mismatch repair deficient; MSI-H, microsatellite instability-high; ORR, objective response rate; OS, overall survival; PD-1, programmed cell death protein 1; PFS, progression-free survival; q4W, every 4 weeks; tx, treatment.

6. Sample size

Simon's 2-stage minimax design was selected for sample size calculation. CR rate from the unacceptable rate of 27.5% to an acceptable rate of 50% with type I error of 0.05 and 80% power. Considering that there is no study on the effect of ICIs as NAC for endometrial cancer and that the evidence is an exploratory study, assumptions previously conducted in colorectal cancer were borrowed. In the first stage, we would enroll 15 patients. If there are 4 or fewer responders, the study will stop for futility. In the second stage, we will enroll an additional 15 patients for a total of 30 patients on study. Efficacy is demonstrated when more than 13 patients show a CR. If more than 13 patients showed a CR in the first stage, the study was terminated without moving to the second stage, considering that the efficacy was proven.

7. Randomization and blinding

Not applicable.

8. Statistical methods

Efficacy analyses/safety analyses are based on modified intent-to-treat approach (patients should receive at least one treatment dose). The primary endpoint is pCR of PD-1 blockade and surgery in subjects with MMRd surgically resectable endometrial cancer. PFS is defined as the time from treatment start until the first documented sign of disease progression or death from any cause; OS is defined as the time from first treatment until death from any cause. PFS and OS will be estimated using the Kaplan-Meier method, and 95% confidence intervals (CIs) will be calculated. Adverse events are graded according to Common Terminology Criteria for Adverse Events version 5.0.

9. Ethics

This study has been approved by the Institutional Review Board (IRB) at Severance Hospital, Yonsei University Health System (IRB number: 4-2023-0001). Permission to conduct this study was obtained from the administrators of all participating facilities. Participants will be obtained written informed consent for participation in this study.

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DISCUSSION

This study will provide evidence on the CR rate of neoadjuvant treatment of nivolumab and surgery in subjects with MMRd surgically resectable endometrial cancer.

Tumors with MMRd have a thousands of somatic mutations, making them susceptible to ICI, such as anti PD-1 or anti PD-L1. Patients with MMRd endometrial cancer treated with ICI have shown significant responses. Le et al. [6] evaluated the PD-L1 blockade in patients with MMRd across 12 different solid tumors. Fifteen patients with MMRd endometrial cancers showed 53% of ORR and a 74% disease control rate. In 49 MSI-H endometrial cancer patients enrolled on the KEYNOTE-158 study received pembrolizumab monotherapy after prior treatment with chemotherapy. ORR was 57.1% (95% CI=42.2–71.2), median PFS was 25.7 months (95% CI=4.9–not reported), and the median OS and duration of response for this cohort is not yet reached [14]. In GARNET trial, the use of dostalimab showed an ORR 43.5% in 129 patients with MMRd endometrial cancer [8]. Based on the results of this study, the US Food and Drug Administration granted breakthrough status for pembrolizumab in treatment of unresectable or metastatic MSI-H/MMRd solid tumors with progression following prior treatment and dostarlimab for patients with MMRd recurrent or advanced endometrial cancer. PD-1 blockade has become integrated into the treatment in recurrent and metastatic MMRd endometrial cancer previously treated with chemotherapy.

Recent studies of using ICIs in NAC for locally advanced cancer rather than metastatic/recurrent cancer, as a key preoperative treatment, are being conducted. Forde et al. [10] showed that high MPR in resectable non-small-cell lung cancer (MPR 38%) treated with up to 2 doses of neoadjuvant nivolumab prior to planned resection of their tumors. Cascone et al. [15] demonstrated high MPR in non-small-cell lung cancer (MPR 38%) treated with nivolumab and ipilimumab, in neoadjuvant setting.

Several studies investigated that NAC with ICI induced tumor regression lead to pathologic and clinical response in MMRd/MSI-H colorectal cancer. In the NICHE study, patients with MMRd colorectal cancers who received ipilimumab and nivolumab before surgery, pathological response was observed in 20/20 (100%) and 12 pCRs [11]. In the NICHE-2 study, patients with non-metastatic MMRd colon cancer were treated with one dose of ipilimumab and two doses of nivolumab and underwent surgery ≤6 weeks of registration [12]. With only 4 weeks of treatment, MPR in 95% of patients with MMRd colon cancer, including 67% pathologic CRs. Liu et al. [16] demonstrated high response rates (100% ORR and 71% pCRs) of MSI-H colorectal cancer in neoadjuvant setting. Recently, Cercek et al. [13] evaluated the PD-1 blockade in patients with MMRd locally advanced rectal cancer. All 12 patients (100%) had a clinical CR, with no evidence of tumor on magnetic resonance imaging. These results indicate that neoadjuvant immunotherapy may have the potential to increase the response rate and improve survival outcomes when used in locally advanced cancer.

The effect of the PD-1 blockade has been demonstrated in non–small-cell lung cancer and MMRd locally advanced colorectal cancer. However, there is no data about the CR rate of PD-1 blockade and surgery in subjects with MMRd surgically resectable endometrial cancer. The results of this study will provide evidence of nivolumab, a PD-1 inhibitor, in patients with MMRd surgically resectable endometrial cancer.

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SUPPLEMENTARY MATERIAL

Data S1

Protocol

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