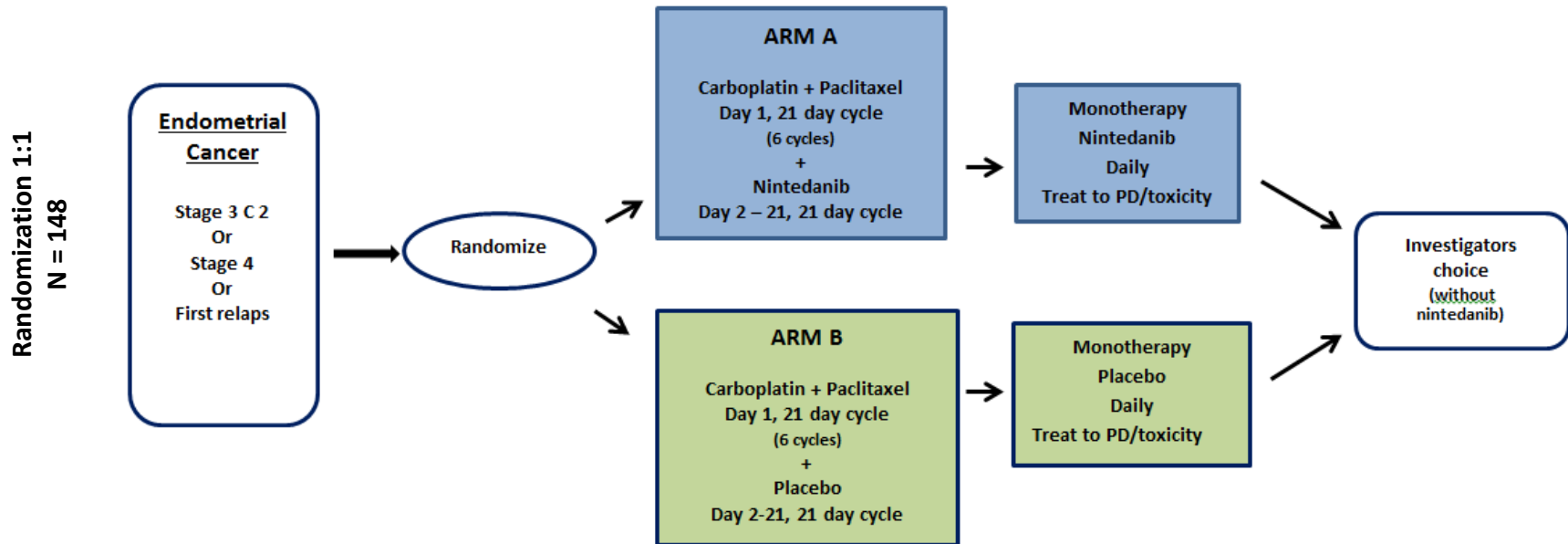


ENGOT-EN1/FANDANGO

A randomised double-blind placebo-controlled phase II trial of first line combination chemotherapy with nintedanib/placebo for patients with advanced or recurrent endometrial cancer.



Sponsor: NSGO
Project Manager: Mette Berensen
Statistician: René DePont Christensen
PI: Mansoor Raza Mirza

Stratification:

- Stage of disease (stage 3C 2 vs. stage 4 vs. recurrent disease)
- Prior adjuvant chemotherapy (yes/no)
- Disease status (Measurable vs. non-measurable disease according to RECIST 1.1)

Primary Objectives: To compare Progression Free Survival (PFS)

ENGOT-EN1/FANDANGO

Inclusion criteria

Histological confirmed endometrial cancer.

- Stage 3C 2
- Stage 4 A & B
- Relapsed after adjuvant therapy for stage 1-3 disease

Prior therapy

2. Patients may have undergone primary surgery.
3. Patients may have received adjuvant chemotherapy for stage 1 – 3.
4. Patients may have received vaginal brachytherapy
5. Patients may have received external beam radiotherapy. Patients who are to be enrolled for stage 3C2 diseases are allowed to receive external beam radiotherapy prior to trial entry.
6. Patients may have received hormonal treatment

Disease status

7. Patients must have measurable disease or non-measurable disease on CT scan according to RECIST 1.1 outside irradiated field. For stage 3C2 disease patients without measurable or non-measurable disease are accepted.

ENGOT-EN1/FANDANGO

Randomized Patients

