

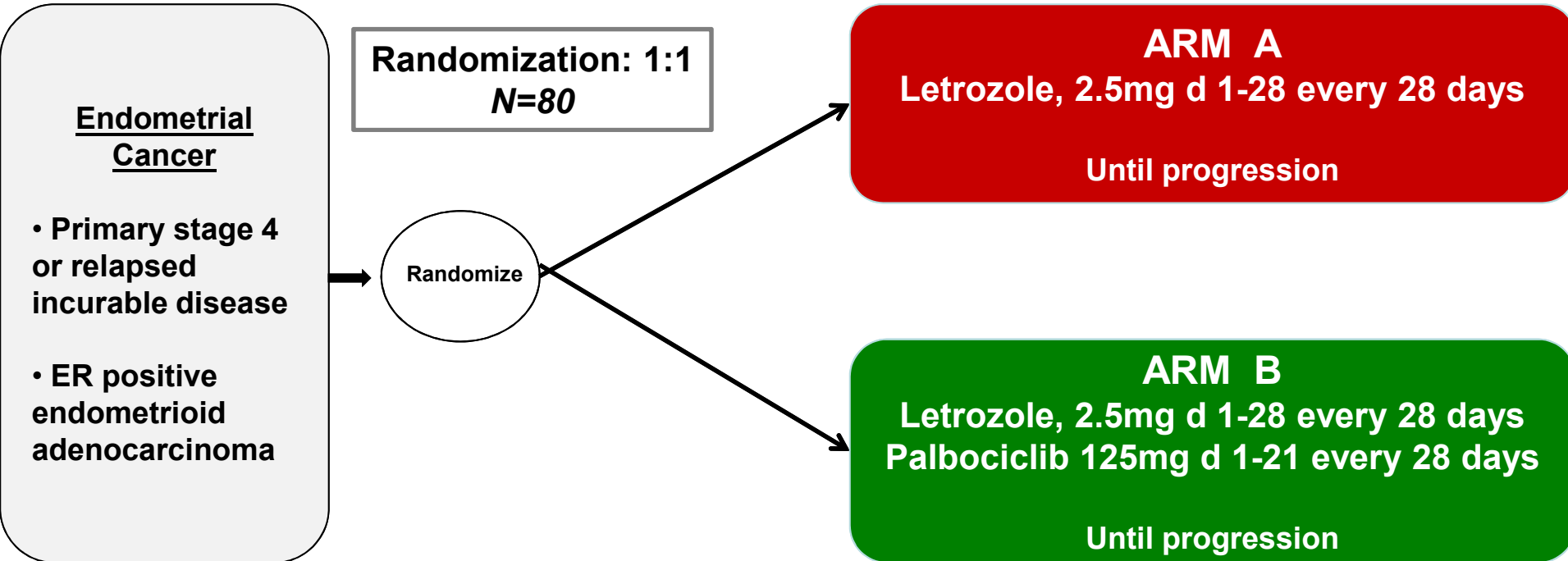


A randomized phase II trial of Palbociclib in combination with letrozole versus letrozole for patients with oestrogen receptor positive recurrent endometrial cancer.



ENGOT-EN3-NSGO/PALEO

Sponsor: NSGO



Stratification:

- Number of prior lines of therapy (primary advanced disease vs. 1st relapse vs. ≥2 relapses)
- Measurable vs. evaluable disease
- Prior use of MPA/Megace (prior MPA/Megace use capped to a maximum of 50%)



Study Population

1. Histological confirmed endometrial cancer of endometrioid type. Mixed tumor histology is allowed if the non-endometrioid component is less than 5%. Tumor must be estrogen receptor positive.

Prior therapy

2. Patients may have received adjuvant chemotherapy for stage 1 or 2.
3. Patients may have received any lines of chemotherapy for primary advanced (stage 3-4) or relapsed disease.
4. Patients may have received external beam radiotherapy, brachytherapy, and surgery.
5. Patient may have received maximum one line of endocrine therapy containing MPA/Megace only.

Disease Status

7. Patients must have measureable disease or evaluable disease on CT scan according to RECIST 1.1 outside irradiated field.



Status

- Contract to be signed by November 2015
- Submissions to authorities starts in January 2016
- Planned first patient in: April 2016