NSGO CLINICAL TRIALS IN ENDOMETRIAL CANCER

UPDATE
A phase III Trial of postoperative chemotherapy or no further treatment for patients with node-negative stage I-II intermediate or high risk endometrial cancer.

**ENGOT-EN2-DGCG / EORTC-55102**

NCT01244789

Sponsor: DGCG

n=678

**Chemotherapy**

Carboplatin-
Paclitaxel x 6

+ Brachytherapy

**Observation**

+ Brachytherapy

1:1 randomization

Supported by

mansoor@rh.regionh.dk
### 5-year survival - FIGO

<table>
<thead>
<tr>
<th>Stage</th>
<th>G1</th>
<th>G2</th>
<th>G3</th>
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<tbody>
<tr>
<td><strong>Stage I</strong></td>
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</tr>
<tr>
<td>Ia</td>
<td>93</td>
<td>91</td>
<td>80</td>
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<tr>
<td>Ib</td>
<td>92</td>
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<td>Ic</td>
<td>91</td>
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<td><strong>Stage II</strong></td>
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<td>IIb</td>
<td>81</td>
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<tr>
<td>Group</td>
<td>Country</td>
<td>No. of Institutions</td>
<td>Activated</td>
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<td><strong>Total</strong></td>
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<td><strong>49</strong></td>
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</table>
A randomized double-blind placebo-controlled phase II trial of first-line combination chemotherapy with Nintedanib for patients with advanced or recurrent endometrial cancer

ENGOT-EN1 / FANDANGO

Randomization: 1:1
n = 148

Endometrial Cancer
Stage 3C2 or
Stage 4 or
First relapse

Randomize

ARM A
Carboplatin + Paclitaxel + Nintedanib

Monotherapy Nintedanib
Treat to PD/toxicity

Investigator’s choice

ARM B
Carboplatin + Paclitaxel + Placebo

Monotherapy Placebo
Treat to PD/toxicity

Stratifications
- stage of disease (stage 3C2 vs. stage 4 vs. recurrent disease)
- Prior adj chemotherapy (yes/no)
- Disease status (Measurable disease vs. non-measurable)

Sponsor: NSGO
Project Manager: Christina Jederud
Statistitian: DePont Christensen
PI: Mirza
Feasibility in collaborative groups completed
Intergroup contracts being signed
NSGO site-contracts being signed
Submissions DK (DHMA & VEK) – completed
Submissions SE (CA & EC) – completed
Submissions to other countries to follow
 (GSO(FIN, NOR, BEL) GINECO, NOGGO)
ALMAC (drug supply): ready by mid July 2016
Expected first patient in: August/September 2016
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**

NCT02730429

**Randomization:** 1:1  
**N=78**

**ARM A**  
Letrozole, 2.5mg d 1-28 every 28 days  
Until progression

**ARM B**  
Letrozole, 2.5mg d 1-28 every 28 days  
Palbociclib 125mg d 1-21 every 28 days  
Until progression

**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%)

Sponsor: NSGO  
Project Manager: Joan Løhndorf  
Statistitian: DePont Christensen  
PI: Mirza  

mansoor@rh.regionh.dk
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

Study Status

Feasibility is being performed

Planned Submission starts in May-June 2016

Planned first Patient in: October 2016