

Protocol synopsis ENSURE trial

Title	ENdometrial cancer SURvivors' follow-up care (ENSURE): Less is more? Randomized controlled trial to evaluate patient satisfaction and cost-effectiveness of a reduced follow-up schedule
Principal investigators	Prof.dr. Lonneke van de Poll-Franse Prof.dr. Roy Kruitwagen Prof.dr. Carien Creutzberg Dr. Nicole Ezendam (coordinating investigator)
Study design	Multicentre randomized controlled trial in the Netherlands
Study population	Women with stage 1A or 1B endometrial cancer, for whom adjuvant radiotherapy is not indicated
Intervention	4 follow-up visits, after 3, 12, 24 and 36 months (intervention) vs. regular follow-up according to the guideline, 10-13 visits during 5 years (control)
Study objective	<p>The aim of this study is to compare a reduced follow-up schedule of 4 visits among low-risk, early-stage endometrial cancer survivors, with the schedule according to the current Dutch guideline that includes 10 to 13 visits, on:</p> <p>Primary outcomes:</p> <ol style="list-style-type: none">1. Patient satisfaction with follow-up care (at 6, 12, 36 and 60 months after completion of primary treatment)2. Costs-effectiveness from the health care perspective (after 3 and 5 years.) <p>Secondary outcomes:</p> <ul style="list-style-type: none">• Health care use -gynaecologist, (specialist) nurse, primary care physician and other health or care services-; adherence to the indicated follow-up protocols; reasons for non-adherence• HRQoL, worry including fear of recurrence, anxiety and depression, and satisfaction with information provision• Health care providers' satisfaction with follow-up schedule (gynaecologist, (specialised) nurse)• Time till recurrence and survival.
Inclusion criteria	<ol style="list-style-type: none">1. Patients with Endometrioid type endometrial carcinoma with stage 1 (FIGO, 2009) disease, with the following combination of stage, age and grade:

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- Stage 1A, any age, grade 1 or 2;
 - Stage 1B, < 60 years, grade 1 or 2 without LVSI;

2. Written informed consent;
3. Sufficient oral and written command of the Dutch language.

- Exclusion criteria**
1. Any other stage and type of endometrial carcinoma
 2. Histological types papillary serous carcinoma or clear cell carcinoma
 3. Uterine sarcoma (including carcinosarcoma)
 4. Radiotherapy for current endometrial carcinoma
 5. Previous malignancy (except for non-melanomatous skin cancer) < 5 yrs
 6. Confirmed Lynch syndrome
 7. Previous pelvic radiotherapy

Number of centers 44

Number of patients 282

Planned We expect inclusion completion in the first months of 2018

Start September 2015
