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

Published: 15-01-2015
Last updated: 21-04-2024

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Uterine, pelvic and broad ligament disorders
Study type	Interventional

Summary

ID

NL-OMON44746

Source
ToetsingOnline

Brief title
ENSURE

Condition

- Uterine, pelvic and broad ligament disorders

Synonym
endometrial cancer, uterine cancer

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit van Tilburg
Source(s) of monetary or material Support: KWF

Intervention

Keyword: cost-effectiveness, endometrial carcinoma, follow-up schedule, quality of life

Outcome measures

Primary outcome

Primary outcomes:

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.)

Secondary outcome

Secondary outcomes:

• 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.

Study description

Background summary

The optimal follow-up schedule for patients with endometrial cancer is unknown. As a result, guidelines in the Netherlands are consensus-based and do not take risk profile into account. Due to current emphasis on providing good care for lower costs, a critical evaluation of current follow-up practices for cancer patients is needed. Endometrial cancer is the most common gynaecological cancer, with 2000 newly diagnosed patients per year in the Netherlands. Today, about 20,000 women living in the Netherlands have survived endometrial cancer. Of them, 7,000 were diagnosed in the past 5 years and are currently receiving follow-up care. Most patients receive 5 year follow-up, with visits each 3 or 4 months in the first 2 years after treatment, each 4 to 6 months in the 3rd year and annually in the 4th and 5th year. Reasons for follow-up include early diagnosis of recurrences -for which curative treatment is available-, signalling consequences of cancer and treatment, psychosocial support, and information provision.

There are multiple reasons to decrease follow-up frequency. First, there is no survival benefit in the detection of asymptomatic recurrences at routine follow-up, compared with symptomatic recurrence or interval detection, probably because the recurrence rate of early-stage endometrial cancer survivors is low (3%) and because most recurrences (70%) present with symptoms. The majority (70-100%) of the recurrences occur within 3 years. Second, consequences of cancer and treatment are found in only 6% of the stage 1 patients who received surgery (hysterectomy and salpingo-oophorectomy) alone. Third, follow-up visits evoke distress around the time of the visits. Finally, alternative follow-up schedules in other cancer populations do not show decreased patient satisfaction or Health-Related Quality of Life (HRQoL). Reasons to retain follow-up are that follow-up is beneficial for patients for reassurance, to provide support for psychosocial, physical and sexual problems, and to provide information.

These findings strongly suggest that most early-stage endometrial cancer patients do not need intensive follow-up to detect recurrences, improve survival or discuss consequences of treatment, but patients may need some follow up to detect information needs and provide psychosocial counselling. Therefore, the current follow-up schedule for low-risk early-stage endometrial cancer patients -about 55% of all patients with endometrial cancer- should be reduced to eliminate unnecessary care, decrease patient worry around visits, prevent wrong patient expectations and save health care costs.

Additionally, it is increasingly recognized that cancer survivors should be provided with tailored information about their disease, treatment, care providers, physical and psychosocial consequences of their cancer and its

treatment, care services and health promotion information. The Institute of Medicine advices the use of Survivorship Care Plans (SCPs) to provide cancer survivors this information. However, large scale implementation of SCPs is currently lacking

To obtain evidence on the effects of a reduced follow-up schedule we propose to conduct a nationwide randomized controlled trial (RCT) to study the effects of a reduced follow-up schedule for patients with endometrial cancer. The research question was encountered in the clinical practice of gynaecologic oncology as an urgent need to critically evaluate the possibilities to implement a reduced follow-up practice for endometrial-cancer survivors. If the reduced follow-up schedule results in a similar patient satisfaction at lower costs, the current guideline will be adapted and the reduced schedule can be implemented throughout the Netherlands

Study objective

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:
Primary outcomes:
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.)

Secondary outcomes:
• 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

Study design

Dutch multicentre randomized controlled trial with a 5 year follow-up. Patients (n=282) are randomized in an intervention group with 4 follow-up visits during 3 years, and a control group with 10-13 follow-up visits during 5 years, according to the Dutch guideline. Patients are asked to fill out a questionnaire at baseline, 6, 12, 36 and 60 months. Patient inclusion will take two years (if 60% of the patients participate).

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 burden and risks

In both arms, patients fill out 5 questionaires, 1 after treatment, after 6 months and after 1, 3 and 5 year. The intervention group has to go less often to the hospital (4 times) in comparison with the control group (10-13 times)

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Patients with Endometrioïd type endometrial carcinoma with stage 1 (FIGO, 2009) disease,

with the following combination of stage, age and grade:
- Stage 1A, any age, grade 1 or 2;
- Stage 1B, < 60 years, grade 1 or 2 without LVS
2. Written informed consent
3. Sufficiënt 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

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	30-09-2015
Enrollment:	282
Type:	Actual

Ethics review

Approved WMO Date:	15-01-2015
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	25-06-2015
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	13-07-2015
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	10-08-2015
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	21-10-2015
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	01-12-2015
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	21-12-2015
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	01-03-2016
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	20-04-2016
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO	

Date:	22-06-2016
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	16-08-2016
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	07-11-2016
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	06-12-2016
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	07-02-2017
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	22-03-2017
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	05-04-2017
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	24-08-2017
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	19-12-2017
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL50713.028.14