

BABY Randomized study
(Prof. Sehouli suggested to be a cohort study)

1. Why (the idea behind it)

Even though endometrial cancer is a cancer mostly diagnosed to women after menopause, now, due to the way of living and to obesity younger women are being diagnosed, who might face the prospect of a hysterectomy before they had a chance to bear children. Some of them are eligible to go through Fertility Sparing Treatment and we are wondering whether a changed life style, with better eating habits, exercise and psychological support can help, as well as other complimentary treatment like acupuncture.

2. What (the question)

What is the compliance to complimentary treatment when offered alongside fertility sparing treatment for early stage endometrial cancer? (Or for all young women with gynecological cancer that go through FST)

Secondary question: How many women that undergo FTS are willing to have complimentary treatment and which kind.

3. Inclusion Criteria

- Women with endometrial cancer who are suitable to undergo FTS. (Prof. Sehouli suggested to include all women (with gynecological cancer) that undergo FTS)
- Women who are willing to have complimentary treatment and to participate in the trial.
- Women with BMI more than 25.
- Women, that never had any children
- Women living in Europe and North America under 45 years old

4. Exclusion criteria

- Women that medically don't fit into the project.
- Women that don't want to be randomized. (This is why Prof. Sehouli suggested that the study should not be randomized but a cohort study instead)
- Language barrier

5. How

Participants will be randomized into 3 arms **Exercise/Diet/Acupuncture**. They will all have psychological support.

Point Zero is one month after initial diagnosis and the trial will start one week after point zero.

The duration is going to be 6 months (+1 week)

The endpoint will be an increase of 10% compliance to all arms.

They have to meet with the prime investigator once a month and with the other investigators once a week.

Exercise→ Women will be offered a cardio and muscle strengthening exercise plan 1 hour/three times a week, according to the women's BMI and physical status. There will be weekly follow ups.

Diet→ women will be offered a low carb, high protein diet through an app so the doctor could monitor the patient with weekly follow ups.

Acupuncture→ women will be offered acupuncture. The type and the frequency will be suggested by the expert

Psychological support → All women will have group therapy every week and private sessions once a month, or if they choose they can have only private sessions once a week.

6. Where

The trial will take place at FST centers and at university hospitals where FST is being conducted.

7. Multidisciplinary team

- ESGO doctor, expert on FST
- Patient advocate who has succeeded
- Doctor expert in Acupuncture
- Dietician
- Trainer
- Psychologist

8. More findings

The difficulties they face and they decide to stop

If they continue after the trial having a healthier life style

If there is a reduction of the side effects of hormonal treatment.

If they add another healthy habit by themselves.

Endometrial cancer team: Kyriaki Mellioy, Jane Ulstrup, Maria Papageorgiou