Behandeling van endometriose met groene thee: Een dubbel blind gerandomiseerde placebo gecontroleerde pilot studie.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20203

Source
NTR

Brief title
TEE-study

Health condition

Endometriosis
Endometriose
Epigallocatechin gallate
Epigallocatechine gallaat
EGCG
Green tea
Groene thee

Sponsors and support

Primary sponsor: VU university medical center
Department of Obstretics and Gynaecology
Source(s) of monetary or material Support: VU university medical center
Department of Obstretics and Gynaecology

Intervention

Outcome measures

Primary outcome

1. To evaluate if the VAS pain scores are lower in patients using EGCG versus placebo treatment;

2. To evaluate if serum Ca-125 level is lower in patients using EGCG versus placebo treatment;

3. To investigate if the total dosage of rescue pain medication is lower in patients using EGCG versus placebo treatment.

Secondary outcome

1. To investigate if the Biberoglu & Behrman severity profile is lower in patients using EGCG versus placebo treatment;

2. To investigate if the menstrual bloodloss is lower in patients using EGCG versus placebo treatment.

Study description

Background summary

A double-blind randomized placebo-controlled pilot trial to evaluate the effect of Epigallocatechin Gallate on VAS pain scores in patients with endometriosis.

Study objective

To evaluate if Epigallocatechin gallate (EGCG) is an effective treatment for pain in endometriosis patients by using Visual Analogue Scores (VAS).

Study design

T=0: Before start with medication at cycle day 2 of the first menstrual cycle;

T=1: 28 days after visit 1;

T=2: 56 days after visit 1;

T=3: 84 days after visit 1.

Intervention

Epigallocatechin gallate capsules 225 mg 3 times a day (total dosage a day of 675 mg) for three months.

Contacts

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Eligibility criteria

Inclusion criteria

1. Signed and dated informed consent;

2. The use of oral contraceptives;

3. Pain associated with visually proven endometriosis determined by diagnostic laparoscopy;

4. Negative pregnancy test;

5. Threshold for pelvic painscore: Minimum of 40 mm on VAS during menstruation at screening;

6. Transvaginal ultrasound within the last 3 months;

7. Good general health (except for endometriosis).

Exclusion criteria

1. Previous/ current use of hormonal agents including GnRH agonists (not within 6 cycles), progestins (not within 3 cycles), hormonal contraception (not within 1 cycle), IUD (mirena), specific oral contraceptives (Diane 35 and three phase oral contraceptives, not within one cycle);

2. Positive pregnancy test;

3. Breastfeeding;

4. Blood coagulation disorders;

5. Liver dysfunction;

6. Usage of any prescription drug;

7. Contra indication for usage of ibuprofen.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-03-2011
Enrollment:	60

Type: Anticipated

Ethics review

Positive opinion
Date: 17-02-2011

Application type: First submission

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
NTR-new	NL2632
NTR-old	NTR2760
Other	METc VUmc : 2010/103
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A