Treatment of Endometriosis with Epigallocatechin gallate: a double-blind randomized placebo-controlled crossover pilot trial.

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To evaluate if Epigallocatechin gallate (EGCG) is an effective treatment for pain in endometriosis patients using oral contraceptives by using Visual Analogue Scores (VAS) * To evaluate if the VAS pain scores are lower after EGCG versus placebo...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Reproductive tract disorders NEC
Study type	Interventional

Summary

ID

NL-OMON39170

Source
ToetsingOnline

Brief title
TEE- study

Condition

- Reproductive tract disorders NEC

Synonym
appearance of endometrial tissue outside the womb., Endometriosis

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum

Source(s) of monetary or material Support: Stichting Wetenschappelijk Onderzoek Gynaecologie

Intervention

Keyword: endometriosis, epigallocatechin gallate, green tea, painscore

Outcome measures

Primary outcome

The difference in VAS pain scores after EGCG versus placebo treatment.

Secondary outcome

1. The difference in the dimension *Pain* of the EHP-30 questionnaire after

using EGCG versus placebo treatment.

2. The difference in serum Ca-125 level after EGCG versus placebo treatment.

3. The difference in total amount of rescue medication during EGCG versus

placebo treatment.

4. The difference in Biberoglu & Behrman severity after EGCG versus placebo

treatment.

5. The total amount of bloodloss during EGCG versus placebo treatment.

Study description

Background summary

Endometriosis is defined as the presence of endometrial-like tissue (which is in normal circumstances only inside the uterus) within the pelvis and other extra-uterine sites. It is a common estrogen dependent disease which is thought to affect up to 10% of women of reproductive age. This can rise up to 35-50% in women presenting with pelvic pain or infertility or both. From our experience of patients in our outdoor clinic (Endometriosis Centre, VU medical centre, Amsterdam), endometriosis patients often notice that drinking a high amount of green tea (15 cups a day or more), relieves their pain symptoms. This raised our interest in this topic because this can be revolutionary in the treatment

of endometriosis.
The regular treatment of endometriosis is surgical, hormonal and/ or usage of pain medication. Green tea seems to be the only non- hormonal therapy, discovered by the patient itself by drinking many cups of tea.
Recently not only the patients experience but also scientific research showed that green tea may be a promising new treatment in endometriosis. It has recently been described that Epigallocatechin gallate (EGCG, the major component of green tea) inhibits estrogen-induced activation of endometrial cells in vitro and causes regression of endometriotic lesions in vivo in hamsters (Laschke 2008). Another publication showed anti-angiogenic effects of EGCG in an experimental mouse model (Xu 2009).The antioxidant activity which removes free radicals and anti-angiogenic effects of EGCG could play a promising role in the reduction of pain and may point to a new non- hormonal treatment for endometriosis in humans without side effects of regular used medication.

Study objective

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

* To evaluate if the VAS pain scores are lower after EGCG versus placebo treatment.
* To evaluate if the dimension *Pain* within the EHP-30 improves after treatment with EGCG versus placebo treatment.
* To evaluate if the serum Ca-125 level is lower after EGCG versus placebo treatment.
* To investigate if the total dosage of rescue pain medication is lower during EGCG versus placebo treatment.
* To investigate if the Biberoglu & Behrman severity profile is lower after EGCG versus placebo treatment.
* To investigate if the total amount of bloodloss is lower during EGCG versus placebo treatment.

Study design

To investigate the effect of EGCG on endometriosis a double-blind randomized placebo-controlled crossover pilot trial (RCT) will be organized. Therefore 30 patients diagnosed with endometriosis using oral contraceptives with persistent pain with VAS scores of at least 40mm, will be invited from our Endometriosis Centre. 15 of these patients will receive EGCG 675mg (= 3 capsules) a day for 2 months, followed by placebo for 2 months. The other 15 patients will first receive placebo capsules for two months, followed by EGCG for two months. In case of severe pain all study patients are able to use their own chosen rescue medication.

This study includes 3 visits to our centre. During each visit a blood sample for the evaluation of the serum Ca-125 level will be taken, and patietns will be asked to fill in a questionnaire on quality of life (EHP-30), menstruation and pain scores(VAS score). Also a gynaecologic investigation will be performed conform Biberoglu & Behrman severity profile. Every day the patient has to fill in a diary for the use of study medication, total use of rescue medication and menstrual blood loss.

Intervention

The dialy use of 3 capsules (or placebo or EGCG). The capsule should be taken 0,5-1 hour before breakfast, afternoon- and evening meal combined with a fair amount of water during 4 subsequent months.

Study burden and risks

The risk of this research is nil if in and exclusion criteria are followed.

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

* Signed and dated informed consent
* Pain associated with visually proven endometriosis determined by diagnostic laparoscopy start of treatment (but not in 6 weeks prior to screening)
* The use of oral contraceptives.
* Persistent endometriosis related pain; Threshold for pelvic painscore: minimum of 40 mm on VAS
* Transvaginal ultrasound within the last 3 months.
* Good general health (except for endometriosis).

Exclusion criteria

* Previous/current use of hormonal agents including:
GnRH agonists (not within 6 cycles), progestins (not within 3 cycles), IUD (mirena), specific oral contraceptives (Diane 35 and three phase oral contraceptives, not within one cycle).
* Breastfeeding
* Blood coagulation disorders
* Pregnancy
* Liver dysfunction
* Usage of any prescription drug

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	31-01-2012
Enrollment:	30
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Epigallocatechin gallate
Generic name:	Epigallocatechin gallate

Ethics review

Approved WMO Date:	24-01-2011
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-02-2011
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-11-2011
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-11-2011
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	08-05-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	

Date:	11-05-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-06-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-06-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
EudraCT	EUCTR2010-023868-41-NL
CCMO	NL31861.029.10

Study results

Date completed:	01-09-2014
Actual enrolment:	7

Summary results
Trial ended prematurely