Levonorgestrel spiraal versus progesteron oraal voor de behandeling van hyperplasie zonder atypie van het endometrium.

Published: 07-01-2009
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Treatment of endometrial hyperplasia by an IUD that contains progesteron is more effective and has less side-effects than the treatment with progesteron oral.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Reproductive neoplasms female benign
Study type	Interventional

Summary

ID

NL-OMON36959

Source
ToetsingOnline

Brief title
HYPROLEV-study

Condition

- Reproductive neoplasms female benign

Synonym
abnormal endometrial tissue, precancer leasion of woomb

Research involving
Human

Sponsors and support

Primary sponsor: obstetrie en gynaecologie
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: endometrium, hyperplasia, levonorgestrel IUD, progesteron

Outcome measures

Primary outcome

endometrial atrofy after treatment

Secondary outcome

less side-effects in the study-group than the control-group

Study description

Background summary

Endometrial hyperplasia without atypie is treated by oral progestron. This treatment has some side-effects. Another way of treating this condiion is by an IUD that contains progesteron. This method is already been investigated and is also effective. We think that this second option (the IUD which contains progesteron) is more effective and is also has less side-effects than the oral treatment. That is why we want to do this ranomized controlled trial. For this study we need to include 90 patients.

Study objective

Treatment of endometrial hyperplasia by an IUD that contains progesteron is more effective and has less side-effects than the treatment with progesteron oral.

Study design

prospective randomized clinical trial

Intervention

One group will be treated bij oral progesteron and the oter group will get a levonorgestrel-IUD.

Study burden and risks

Patients are four times asked to fill in a form which will take about 10-15 minutes each time.

There are no risks for the patient in this study.

Contacts

Public
Selecteer

Debyelaan 25
6202 AZ Maastricht
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Scientific
Selecteer

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

endometrial hyperplasia (simple and complex), Dutch language

Exclusion criteria

endometrial cancer, hyperplasia with atypie, history of hyperplasia, contra-indication for treatment with progesteron, biopt not possible for any reason

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-04-2011
Enrollment:	90
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Mirena
Generic name:	Levonorgestrel IUD
Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	provera
Generic name:	medroxyprogesteron
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	07-01-2009
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	21-07-2009
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	23-06-2010
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	09-02-2011
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	21-03-2011
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	26-04-2011
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	EUCTR2008-006715-21-NL
CCMO	NL24978.068.08