Wat zijn de effecten van het middel Duogestan® op de kwaliteit van leven?

No registrations found.

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

Summary

ID

NL-OMON22707

Source
NTR

Brief title
WHISPER-1

Health condition

Menopause, menopauze, overgang

Sponsors and support

Primary sponsor: Besins Healthcare
Source(s) of monetary or material Support: fonds=sponsor

Intervention

Outcome measures

Primary outcome

The primary objective is to assess if Duogestan ® can lead to a 20% improvement of the health related quality of life compared to baseline. We will explore the overall quality of life, as well as the individual components of the quality of life questionnaire.

Secondary outcome

Secondary objectives include the bleeding pattern, the menopausal symptoms and the evaluation of safety and tolerability of Duogestan ® treatment.

Study description

Background summary

N/A

Study objective

Duogestan® leidt in symptomatische, vroeg postmenopausale vrouwen tot een verbetering in kwaliteit van leven van 20%.

Study design

There will be a total of 6 visits. The first visit being the screening and the following 5 visits being measuring moments.

Intervention

Duogestan® (hormone replacement therapy).

Contacts

Public
Academisch Ziekenhuis Maastricht
Secr. Obstetrie/gynaecologie
Postbus 5800
T. Ekhart
Maastricht 6202 AZ
The Netherlands
+31 (0)43-3882101
Scientific
Academisch Ziekenhuis Maastricht
Secr. Obstetrie/gynaecologie
Postbus 5800
T. Ekhart
Maastricht 6202 AZ
The Netherlands
+31 (0)43-3882101

Eligibility criteria

Inclusion criteria

1. Postmenopausal women: last menstrual period between 6 months and maximum 5 years ago, FSH levels > 35 IU/L and estradiol levels < 20 picograms/mL (cut offs defined by central laboratory: “Klinisch Chemisch Laboratorium” at MUMC);

2. Positive progesterone challenge test;

3. Endometrium thickness less than 5 mm;

4. Age between 45-55 years;

5. Menopausal discomfort, more specifically hot flushes (2 or more hot flushes per day since at least three months);

6. Intact uterus.

Exclusion criteria

1. Previous use of any hormone replacement therapy for a duration of more than 3 years;

2. Use of medication known to interact with 17 ß-estradiol or micronized progesterone;
- Substances known to induce drug-metabolising enzymes, particularly anticonvulsants (e.g. phenobarbital, phenytoin, carbamazepine) and anti-infectives (e.g. rifampicin, fifabutin, nevirapine, efavirenz):

A. Ritonavir and nelfinavir;

B. Herbal preparations containing St. John’s Wort (Hypericum perforatum);

3. Known contra-indications for Duogestan®:

A. Known, past or suspected breast cancer;

B. Known or suspected estrogen-dependent malignant tumours (e.g. endometrial cancer);

C. Undiagnosed genital bleeding;

D. Untreated endometrial hyperplasia;

E. Previous idiopathic or current venous trhomboembolism (deep vein thrombosis, pulmonary

embolism);

F. Active or recent arterial thromboembolic disease (e.g. angina, myocardial infarction);

G. Acute liver disease or a history of liver disease, until liver function tests have returned to normal;

H. Known hypersensitivity to the active substances or to any of the excipients;

I. Porphyria.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2009
Enrollment:	100
Type:	Anticipated

Ethics review

Positive opinion

Date:	30-01-2009
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	NL1568
NTR-old	NTR1648
Other	MEC Maastricht : 08-2-130
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A