Women*s Hormonal Intervention Study in early Postmenopause of Estradiol-progesterone Replacement therapy - effects on quality of life

Published: 10-08-2009
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To evaluate health related QoL under an oral cyclic treatment with physiological steroid hormones: Duogestan®.

Ethical review	Not approved
Status	Will not start
Health condition type	Endocrine disorders of gonadal function
Study type	Interventional

Summary

ID

NL-OMON34007

Source
ToetsingOnline

Brief title
WHISPER-1

Condition

- Endocrine disorders of gonadal function

Synonym
Menopause

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Besins Healthcare (Brussel - Belgie),Besins

Healthcare (Farmaceutische industrie)

Intervention

Keyword: Estradiol, Hormone replacement therapy, Progesterone, Quality of life

Outcome measures

Primary outcome

Health related QoL assessed with the Dutch validated versions of the Women*s

Health Questionnaire (WHQ) and the European Quality of life instrument

(EuroQol).

Secondary outcome

Bleeding pattern and menopausal symptoms assessed with a daily diary.

Study description

Background summary

The menopausal transition and the menopause are responsible for important quality of life (QoL) and preventive health challenges. Different publications show that hormone replacement therapy (HRT) improves quality of life through the reduction of both the number and severity of menopausal symptoms.

Study objective

To evaluate health related QoL under an oral cyclic treatment with physiological steroid hormones: Duogestan®.

Study design

This is an open-label longitudinal study.

Intervention

Each patient will receive 13 cycles of 28 days Duogestan® (1mg micronized 17 β-estradiol, 200mg micronized progesterone), each cycle consisting of 25 days of treatment followed by 3 days free of treatment.

Study burden and risks

Each patient has to take Duogestan® during one year. The number of site visits is six. During each visit the WHQ and EuroQol will be completed. In between the site visits, the patients keep a bleeding diary. Blood samples will be taken three times. All patients will undergo a physical examination and a vaginal ultrasound. If necessary, endometrial biopsy will be performed. A mammography will be carried out if the patient has not had a mammography before, or if the last mammography is dated more than one year ago.
Risks associated with the study include possible risks of Duogestan® treatment (occurrence of side effects and increased risk of breast cancer after long-term (>5 years) use) and possible side effects of blood drawing.
Since HRT relieves symptoms of menopause and therefore improves quality of life, patients might benefit from treatment with Duogestan®.

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

1. Postmenopausal women: last menstrual period between 6 months and maximum 2 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. Endometrium thickness less than 5 mm
3. Negative progesterone challenge test
3. 4. Age between 45-55 years
5. Menopausal symptoms including at least moderate to severe vasomotor symptoms (defined as at least 35 moderate (sensation of heat with sweating, able to continue activity) to severe (sensation of heat with sweating, causing cessation of activity) hot flushes and/or night sweats per week
6. Intact uterus
7. Normal mammography within the last 12 months
8. Able to understand and sign informed consent form

Exclusion criteria

1. Previous use of any hormone replacement therapy; except the use of estriol or phyto-estrogens
2. BMI > 35
3. Use of oral contraceptives during the last 2 months
4. Use of hormonal intra uterine device or implant during the last 2 months
5. Known contra-indications for Duogestan®:
- Known, past or suspected breast cancer;
- Known or suspected estrogen-dependent malignant tumours (e.g. endometrial cancer);
- Undiagnosed genital bleeding;
- Untreated endometrial hyperplasia;
- Previous idiopathic or current venous trhomboembolism (deep vein thrombosis, pulmonary embolism);
- Active or recent arterial thromboembolic disease (e.g. angina, myocardial infarction);
- Acute liver disease or a history of liver disease, until liver function tests have returned to normal;
- Known hypersensitivity to the active substances or to any of the excipients;
- Porphyria
6. 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)
- Ritonavir and nelfinavir
- Herbal preparations containing St. John*s Wort (Hypericum perforatum)
7. Participation in an investigational study within 30 days prior to administration of the study medication

Study design

Design

Study phase:	4
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	100
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Duogestan®
Generic name:	17 β-Estradiol - micronized progesterone

Ethics review

Approved WMO

Date:	10-08-2009
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Not approved

Date:	16-09-2009
Application type:	First submission
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	EUCTR2008-008311-26-NL
CCMO	NL26313.068.09
Other	Registratie bij clinicaltrials.gov in progress