

# Prevention of osteoporosis in normogonadotropic anovulatory women

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 31/08/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 07/02/2017	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Anovulation is a condition where the ovary does not release an egg each month as part of a woman's normal cycle in her reproductive years. Anovulatory women usually have oligomenorrhoea or amenorrhoea (irregular or absent menstruation). Anovulatory women of reproductive age need to be protected against bone loss and osteoporosis, a condition that weakens bones, making them fragile and more likely to break. Women with chronic (long-term) anovulation are usually hypoestrogenic (lower than normal level of estrogen), and it is not known whether oral contraceptives or hormone replacement therapy (HRT) have a protective effect on bone loss and the development of osteoporosis. The aim of this study is to compare the effects of oestrogen combined with a progestogen in the form of either an oral contraceptive or HRT on the bone mineral density of anovulatory women.

### Who can participate?

Women aged 20-45 with anovulation (either 12 months of amenorrhoea or a menstrual cycle of average length 35 days or longer in the previous 12 months)

### What does the study involve?

Participants are randomly allocated to be treated with either the Microgynon oral contraceptive pill or Femoston HRT tablets daily for a period of 12 months. All participants visit the clinic four times during the study for medical tests. Bone mineral density is measured in either the spine or femoral neck (thigh bone) using an x-ray scan. Blood samples are taken at two of these visits.

### What are the possible benefits and risks of participating?

The results will help improve medical knowledge. Participants get two free measurements of their bone mineral density, which may help them decide whether to use the treatment long term. Participants also get information from the additional blood tests. All drugs have the potential to cause side effects in some patients. Many women worldwide use either oral contraceptives or HRT. Serious side effects are most commonly found in older women who have underlying health problems, who therefore won't be included in the study. The most common side effects of both medications are nausea and breast tenderness. During every visit, the investigator closely monitors participants for side effects. The risks of blood drawing are minimal but include the temporary pain of the needle stick, occasional bruising and rarely

inflammation of the vein. The study is stopped if participants have unacceptable side effects or adverse reactions. Any significant findings discovered during this study will be provided to participants. Both preparations to be used in this study are commonly prescribed already. They are not new drugs. Both preparations have a low risk of venous thrombosis (blood clots) and breast cancer with long-term use. Venous thrombosis is more common in women at risk, who are usually older and not healthy, not like the women in this study. The researchers believe it is unethical not to treat these women, as if left untreated, they risk endometrial hyperplasia (where the lining of the womb becomes thicker) and premature osteoporosis, with associated fractures, illness and possible death.

Where is the study run from?

The Li Ka Shing O&G clinic (Hong Kong)

When is the study starting and how long is it expected to run for?

September 2009 to September 2012

Who is funding the study?

The Chinese University of Hong Kong

Who is the main contact?

Cindy Law

cindylaw@cuhk.edu.hk

## Contact information

**Type(s)**

Scientific

**Contact name**

Prof Christopher Haines

**Contact details**

The Chinese University of Hong Kong

Prince of Wales Hospital

Shatin

Hong Kong

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

CRE-2009.385-T

## Study information

**Scientific Title**

A pilot study to compare the effect of oestrogen combined with a progestogen in the form of either an oral contraceptive (OC) or hormone replacement therapy (HRT) on bone mineral density (BMD) in normogonadotropic hypoestrogenic anovulatory women

**Study objectives**

That oral contraceptives and hormone replacement therapy are equally effective in preventing osteoporosis in normogonadotropic anovulatory women.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Clinical Research Ethics Committee of the Chinese University of Hong Kong, 23/08/2009, ref: CRE-2009.385-T

**Study design**

Prospective randomised controlled trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

Not available in web format, please use the contact details to request a patient information sheet

**Health condition(s) or problem(s) studied**

Osteoporosis

**Interventions**

Randomization to treatment with either:

1. Microgynon 30 ED OC (ethinylestradiol 0.03 mg, levonorgestrel 0.15 mg daily for 21 days with 7 days lactose tablet)
2. Femoston (oestradiol 2 mg daily for 14 days, oestradiol 2 mg daily plus dydrogesterone 10 mg daily for 14 days)

**Intervention Type**

Drug

**Phase**

Not Applicable

**Drug/device/biological/vaccine name(s)**

Ethinylestradiol, levonorgestrel, oestradiol, dydrogesterone

**Primary outcome measure**

BMD in either spine or femoral neck, measured using dual-energy x-ray absorptiometry (DEXA)

**Secondary outcome measures**

1. Estimate of bone formation by measurement of serum bone-specific alkaline phosphatase (sBSAP)
2. Estimate of bone resorption by measurement of serum degradation products of C-terminal telopeptides of type 1 collagen (sCTX)
3. Well-being, measured using the Women's Health Questionnaire (WHQ)

**Overall study start date**

16/09/2009

**Completion date**

30/09/2012

## **Eligibility**

**Key inclusion criteria**

1. Women aged 20-45 years
2. Either 12 months of amenorrhoea or a menstrual cycle of average length 35 days or longer in the previous 12 months
3. At baseline Follicle-stimulating hormone (FSH) > 3.5 IU/L, < 10 IU/L
4. Luteinizing hormone (LH) > 2.4 IU/L, < 12.6 IU/L
5. E2 < 201 pmol/L
6. PRL < 496 mIU/L

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Female

**Target number of participants**

100

**Key exclusion criteria**

1. On exogenous hormones within previous 3 months
2. Any contraindication to the use of female hormones
3. Any condition making it likely that they cannot complete the study
4. Hypergonadotropic or hypogonadotropic hypogonadism or hyperprolactinaemia as defined by abnormal FSH, LH or Prolactin concentrations
5. Any personal or strong family history of breast cancer or endometrial cancer
6. History of pulmonary or venous thromboembolism

**Date of first enrolment**

16/09/2009

**Date of final enrolment**

30/09/2012

## **Locations**

**Countries of recruitment**

Hong Kong

**Study participating centre**

The Chinese University of Hong Kong

Shatin

Hong Kong

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## **Sponsor information**

**Organisation**

The Chinese University of Hong Kong (Hong Kong)

**Sponsor details**

Direct Grant for Research

Medicine Panel

Shatin

Hong Kong

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**Sponsor type**

University/education

**Website**

<http://www.cuhk.edu.hk/english/>

**ROR**

<https://ror.org/00t33hh48>

## **Funder(s)**

**Funder type**

University/education

**Funder Name**

Chinese University of Hong Kong (ref: 2041471)

**Alternative Name(s)**

The Chinese University of Hong Kong, , CUHK

**Funding Body Type**

Government organisation

**Funding Body Subtype**

Universities (academic only)

**Location**

Hong Kong

## **Results and Publications**

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date****Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration