ISRCTN55207514 https://doi.org/10.1186/ISRCTN55207514

Prevention of osteoporosis in normogonadotropic anovulatory women

Submission date
22/08/2012

Recruitment status
No longer recruiting

Registration date
31/08/2012

Overall study status
Completed

Last Edited
07/02/2017

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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
-

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
-

Sponsor information

Organisation
The Chinese University of Hong Kong (Hong Kong)

Sponsor details
Direct Grant for Research
Medicine Panel
Shatin
Hong Kong
-

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