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A randomised, controlled trial to compare the effects of systemic HRT (tibolone) and vaginal oestrogen (estring) upon the overactive bladder in postmenopausal women.

Submission date
30/09/2005

Recruitment status
No longer recruiting

Registration date
30/09/2005

Overall study status
Completed

Last Edited
08/09/2015

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Surya Gupta-Wright

Contact details
Academic Dept of Womens Health GKT
HRT Research
Guy's Hospital
St Thomas' Street
London
United Kingdom
SE1 9RT

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0013146054

Study information

Scientific Title
A randomised, controlled trial to compare the effects of systemic HRT (tibolone) and vaginal oestrogen (estring) upon the overactive bladder in postmenopausal women.

Study objectives
To ascertain if symptoms and markers of an overactive bladder can be improved by the use of topical or systemic hormone replacement therapy (HRT) in postmenopausal women.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised double-blind controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Urological and Genital Diseases: Overactive bladder

Interventions
A double-blind randomised study, patients will be randomised to systemic HRT (tibolone) and placebo rings, 40 will receive placebo tablets and oestradiol releasing vaginal rings (estring), 40 will receive placebo tablets and placebo rings. Women will be followed up for one year and will be required to make 7 visits in total. The women will be provided with an information leaflet regarding the study and be given the opportunity to ask any questions before written consent is obtained. Prior to inclusion, the women will have a medical history recorded, blood pressure measured and a urine sample tested by dipstick to exclude the presence of a urinary tract infection. A positive result for blood, nitrites or protein will require further investigation.

Baseline measurements of quality of life questionnaire, transvaginal ultrasound scan to assess bladder wall thickness, urine flow rate and residual urine volume and completion of a urinary symptom diary will be recorded prior to random allocation of treatment. Subjects will be followed for one year, attending the clinic every 3 months.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Primary outcome will be quality of life assessed using the Kings Health Questionnaire (KHQ). Objective measures will include symptom diaries for 48 hours, bladder wall thickness and urine dipstick.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/07/2003

Completion date
01/09/2005

Eligibility

Key inclusion criteria
120 postmenopausal women aged 60 or over who are suffering from overactive bladder symptoms.

Participant type(s)
Patient

Age group
Senior

Sex
Female

Target number of participants
120

Key exclusion criteria
1. Women aged < 60 years
2. Pre-menopausal women
3. Women who have had a history of uncontrolled metabolic diseases, neurological conditions, permanent catheterisation, chronic urinary tract infections
4. Patients who have any contraindications to the use of HRT
5. Patients who have suffered a major prolapse (as defined by The International Continence

Society)
6. Patients who have taken hormone replacement therapy within the last 6 months

Date of first enrolment
01/07/2003

Date of final enrolment
01/09/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Guy's Hospital
London
United Kingdom
SE1 9RT

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Guy's and St. Thomas' NHS Foundation Trust (UK)

Funder Name
NHS R&D Support Funding (UK)

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