

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	<input type="checkbox"/> Prospectively registered
Registration date 30/09/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 08/09/2015	Condition category Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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