

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	☐ Prospectively registered
Registration date 30/09/2005	Overall study status Completed	☐ Protocol
Last Edited 08/09/2015	Condition category Urological and Genital Diseases	☐ 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

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Additional identifiers

Protocol serial number

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

Primary study design

Intentional

Study design

Randomised double-blind controlled trial

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Senior

Sex

Female

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

United Kingdom

England

Study participating centre

Guy's Hospital
London
United Kingdom
SE1 9RT

Sponsor information

Organisation
Department of Health

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration