

# The effect of oestrogen replacement therapy on urinary tract dysfunction and urogenital collagen structure in postmenopausal women with stress incontinence

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| <b>Submission date</b><br>23/01/2004   | <b>Recruitment status</b><br>No longer recruiting            | <input type="checkbox"/> Prospectively registered    |
| <b>Registration date</b><br>23/01/2004 | <b>Overall study status</b><br>Completed                     | <input type="checkbox"/> Protocol                    |
| <b>Last Edited</b><br>15/12/2008       | <b>Condition category</b><br>Urological and Genital Diseases | <input type="checkbox"/> Statistical analysis plan   |
|  |  | <input checked="" type="checkbox"/> Results          |
|  |  | <input type="checkbox"/> Individual participant data |

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Mr Simon Jackson

### Contact details

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Bristol  
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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

## Secondary identifying numbers

R/03/16-12-94/JACKSON/D

# Study information

## Scientific Title

## Study objectives

To investigate the effect of hormone replacement therapy on post-menopausal urinary stress incontinence.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Not provided at time of registration

## Study design

Randomised controlled trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Not specified

## Study type(s)

Not Specified

## Participant information sheet

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

Urological and genital diseases: Incontinence

## Interventions

1. Six months therapy with oestradiol valerate 2 mg daily
2. Placebo

## Intervention Type

Other

## Phase

Not Specified

## Primary outcome measure

Assessment prior to treatment and upon study completion with the SF-36 health status questionnaire, the Bristol Female Lower Urinary Tract Symptoms questionnaire, a one week urinary diary, one hour perineal pad test, cystometry and urethral profilometry.

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

01/08/1995

**Completion date**

31/07/1996

## Eligibility

**Key inclusion criteria**

Post-menopausal women with genuine stress incontinence, not taking hormone replacement therapy

**Participant type(s)**

Patient

**Age group**

Not Specified

**Sex**

Female

**Target number of participants**

Added December 2008: 37

**Key exclusion criteria**

Not provided at time of registration

**Date of first enrolment**

01/08/1995

**Date of final enrolment**

31/07/1996

## Locations

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**North Bristol NHS Trust**  
Bristol  
United Kingdom  
BS10 5NB

## **Sponsor information**

### **Organisation**

NHS R&D Regional Programme Register - Department of Health (UK)

### **Sponsor details**

The Department of Health  
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.doh.gov.uk>

## **Funder(s)**

### **Funder type**

Government

### **Funder Name**

NHS Executive South West (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

**Study outputs**

| Output type                     | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | results | 01/07/1999   |            | Yes            | No              |