ISRCTN06344732 https://doi.org/10.1186/ISRCTN06344732

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

Submission date
23/01/2004

Recruitment status
No longer recruiting

Registration date
23/01/2004

Overall study status
Completed

Last Edited
15/12/2008

Condition category
Urological and Genital Diseases

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

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
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?
Results article	results	01/07/1999		Yes	No