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Evaluation of the efficacy of topical oestrogen therapy in the management of urinary dysfunction

Submission date	Recruitment status	[ ] Prospectively registered
25/10/2000	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
25/10/2000	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
20/07/2012	Urological and Genital Diseases	[ ] 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

Protocol serial number
G9410491

Study information

Scientific Title

Study objectives
To evaluate the effect of topical oestrogen therapy on post-menopausal women with incontinence and bladder storage abnormality symptoms.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

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

Interventions
1. Active: Topical vaginal oestrogen in the form of vaginal slow releasing rings (Estring)
2. Control: Matching placebo

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Clinical assessment using urinary diaries and 24 hour home pad tests.

Key secondary outcome(s)
Not provided at time of registration

Completion date
01/06/2001

Eligibility

Key inclusion criteria
1. Urinary dysfunction measured clinically (incontinence, nocturia, frequent voiding, urinary urgency)
2. Post-menopausal women

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Female

Key exclusion criteria
1. Pregnancy
2. Malignancy
3. Fistula
4. Those already in receipt of treatment
5. Those already on hormone replacement therapy
6. Undiagnosed vaginal bleeding
7. Oestrogen dependent tumour
8. Active thrombo-embolic disease

Date of first enrolment
01/09/1999

Date of final enrolment
01/06/2001

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Department of Epidemiology and Public Health
Leicester
United Kingdom
LE1 2TP

Sponsor information

Organisation
Medical Research Council (MRC) (UK)

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (MRC) (UK)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration