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

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

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
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

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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 measure
Clinical assessment using urinary diaries and 24 hour home pad tests.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/09/1999

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

Age group
Not Specified

Sex
Female

Target number of participants
432

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
England

United Kingdom

Study participating centre
Department of Epidemiology and Public Health
Leicester
United Kingdom
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Sponsor information

Organisation
Medical Research Council (MRC) (UK)

Sponsor details
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clinical.trial@headoffice.mrc.ac.uk

Sponsor type
Research council

Website
http://www.mrc.ac.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, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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