

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
Registration date 25/10/2000	Overall study status Completed	☐ Protocol
Last Edited 20/07/2012	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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Contact details

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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

Study design

Randomised controlled trial

Primary study design

Interventional

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