

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

Submission date 25/10/2000	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 25/10/2000	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 20/07/2012	Condition category Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr C McGrother

Contact details

Department of Epidemiology and Public Health
University of Leicester
22-28 Princess Road West
Leicester
United Kingdom
LE1 2TP

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
LE1 2TP

Sponsor information

Organisation

Medical Research Council (MRC) (UK)

Sponsor details

20 Park Crescent
London
United Kingdom
W1B 1AL
+44 (0)20 7636 5422
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