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Women's International Study of long Duration Oestrogen after Menopause

Submission date	Recruitment status	[_] Prospectively registered
25/10/2000	Stopped	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
25/10/2000	Stopped	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
07/11/2022	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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
E185/126

Study information

Scientific Title
Women's International Study of long Duration Oestrogen after Menopause

Acronym
WISDOM

Study objectives
To establish the balance between benefits and risks of long-term hormone replacement therapy, HRT, in post-menopausal women.

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
Obstetrics and gynaecology

Interventions
Long-term hormone replacement therapy vs placebo. Stopped in 2002 after similar study showed risks to patients (reported by the BBC)

Intervention Type
Other

Phase
Not Specified

Primary outcome measure

Fatal and non-fatal ischaemic heart disease and unstable angina, major osteoporotic fractures, breast cancer.

Secondary outcome measures
Cancers, stroke, deep vein thrombosis deaths, quality of life, cost effectiveness plus other conditions possibly affected by HRT.

Overall study start date
01/10/1999

Completion date
30/09/2016

Reason abandoned (if study stopped)
Objectives no longer viable

Eligibility

Key inclusion criteria
Postmenopausal women aged 50-69 years

Participant type(s)
Patient

Age group
Senior

Sex
Female

Target number of participants
34,000 - 22,000 from the UK. Recruitment suspended 17/10/02.

Key exclusion criteria
1. Premenopausal
2. History of endometriosis or endometrial hyperplasia in women with a uterus
3. Breast cancer
4. BrCa 1 and 2 carriers
5. Melanoma ever
6. Invasive cancer within 10 years (except basal and squamous cell carcinoma)
7. Meningioma
8. Currently active liver disease
9. Severe renal impairment
10. Gall bladder disease unless cholescystectomy
11. DVT, PE, RVO
12. Otosclerosis
13. Porphyria, history of hepatitis B or HIV
14. Fasting triglyceride greater than 5.5 millimoles per litre; current treatment with selective oestrogen receptor modulators (e.g. tamoxifen)

Date of first enrolment
01/10/1999

Date of final enrolment
30/09/2016

Locations

Countries of recruitment
Australia

England

New Zealand

United Kingdom

Study participating centre
MRC Epidemiology and Medical Care Unit
Harrow Middlesex
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Sponsor information

Organisation
Medical Research Council (MRC) (UK)

Sponsor details
20 Park Crescent
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+44 (0)20 7636 5422
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Sponsor type
Research council

Website
http://www.mrc.ac.uk

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (UK) (ref: E185/126)

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

Funder Name
British Heart Foundation (UK) (ref: RG/94006)

Alternative Name(s)
the_bhf, The British Heart Foundation, BHF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

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
Not provided at time of registration

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		01/03/2004		Yes	No
Results article		26/02/2007		Yes	No
Other publications	Main morbidities recorded	04/08/2007		Yes	No
Other publications	Health related quality of life results	21/08/2008		Yes	No