

# Women's International Study of long Duration Oestrogen after Menopause

<b>Submission date</b> 25/10/2000	<b>Recruitment status</b> Stopped	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 25/10/2000	<b>Overall study status</b> Stopped	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 07/11/2022	<b>Condition category</b> Urological and Genital Diseases	<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

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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 cholecystectomy
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

United Kingdom

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## **Sponsor information**

**Organisation**

Medical Research Council (MRC) (UK)

**Sponsor details**

20 Park Crescent

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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 (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?
<a href="#">Results article</a>	Main morbidities recorded	01/03/2004		Yes	No
<a href="#">Results article</a>		26/02/2007		Yes	No
<a href="#">Other publications</a>		04/08/2007		Yes	No
<a href="#">Other publications</a>	Health related quality of life results	21/08/2008		Yes	No