

# Hormone replacement therapy and cardiovascular disease: influence of oestrogen replacement therapy on chest pain

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<b>Registration date</b> 23/01/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 24/10/2019	<b>Condition category</b> Circulatory System	<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 J McLenachan

### Contact details

Leeds General Infirmary  
Department of Cardiology  
Great George Street  
Leeds  
United Kingdom  
LS1 3EX  
+44 (0)113 2926476  
Jim.McLenachan@leedsth.nhs.uk

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

## Study information

### Scientific Title

Hormone replacement therapy and cardiovascular disease: influence of oestrogen replacement therapy on chest pain

### Study objectives

Angina in post-menopausal women is a common clinical problem that is often under-investigated and under-treated. While most women with angina have atherosclerotic coronary disease, many have angina with anatomically normal coronary arteries (so-called Syndrome X). Those women with angina and coronary artery disease have a high risk of major cardiovascular events including unstable angina, myocardial infarction and death. Indeed, recent evidence suggests that while coronary disease is declining in men, the incidence of major events continues to rise in women, and may equal that of men in less than two decades. Women with angiographically normal coronary arteries present a different problem; although they have a good prognosis, their symptoms do not respond well to conventional anti-angina therapy and their morbidity and hospital re-admission rate is high. Hormone replacement therapy (HRT) with oestrogen reduces the incidence of cardiac events in post-menopausal women by up to 50%, by mechanisms that have not been elucidated. Interest has recently focused on the functions of the innermost layer of the coronary artery, the coronary endothelium. In health, the endothelial cells cause the artery to dilate in response to a number of physical and chemical stimuli. This function, called endothelium-dependant vasodilation, is lost in the early phase of coronary atherosclerosis and may precipitate further vascular damage. In animal models, HRT given to oophorectomised females can restore normal endothelial function, and may retard the development of atherosclerosis. An analogous abnormality in the endothelial control of coronary blood flow has been identified in Syndrome X. In neither case has the effect of HRT on coronary artery responsiveness been studied in humans. Nor has there been investigation of the effect of HRT on symptoms (i.e. chest pain, exercise tolerance) in either women with or without coronary disease. We plan to assess the influence of HRT on coronary artery responses in post-menopausal women with angina, both with and without coronary artery disease, in an unblinded single angiographic study. Ischaemic heart disease accounts for 24% of all deaths in women aged between 55-74, being the largest single cause of death in this group. The potential benefit to the nation, in both health and financial terms, of more effective therapy and prevention of this burden of disease is great. This study aims to examine mechanisms by which HRT might prevent death and other major cardiovascular events, as well as exploring for the first time the therapeutic potential of HRT in the treatment of chest pain in with and without coronary artery disease. The information acquired may provide the basis for larger controlled trials of HRT as symptomatic and preventative therapy for heart disease 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**

Cardiovascular diseases: heart disease

**Interventions**

Not provided at time of registration

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome measure**

Not provided at time of registration

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

08/01/1994

**Completion date**

30/09/1996

**Eligibility**

**Key inclusion criteria**

Post-menopausal women with angina

**Participant type(s)**

Patient

**Age group**

Not Specified

**Sex**

Female

**Target number of participants**

Not provided at time of registration

**Key exclusion criteria**

Not provided at time of registration

**Date of first enrolment**

08/01/1994

**Date of final enrolment**

30/09/1996

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Leeds General Infirmary**

Leeds

United Kingdom

LS1 3EX

## **Sponsor information**

**Organisation**

NHS R&D Regional Programme Register - Department of Health (UK)

**Sponsor details**

The Department of Health

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

+44 (0)20 7307 2622

dhmail@doh.gsi.org.uk

**Sponsor type**

Government

**Website**

<http://www.doh.gov.uk>

# Funder(s)

## Funder type

Government

## Funder Name

NHS Executive Northern and Yorkshire (UK)

# 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