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

Submission date 23/01/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 23/01/2004	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 24/10/2019	**Condition category** Circulatory System	[_] Individual participant data [_] 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

VCO500 J458 448505

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 analagous 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
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Sponsor information

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

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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