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The Women's Hormone Intervention Secondary Prevention Pilot Study

Submission date 25/10/2000	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 25/10/2000	**Overall study status** Completed	
Last Edited 11/09/2008	**Condition category** Circulatory System	

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
G9811667

Study information

Scientific Title

Acronym
WHISP

Study objectives
To determine the safety and tolerability of hormone replacement therapy (HRT) after acute myocardial infarction (MI) in post-menopausal women

Ethics approval required
Old ethics approval format

Ethics approval(s)
Added 18/07/2007: North Thames Multicentre Research Ethics Committee and the Local Research Ethics Committee at each centre.

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
Acute myocardial infarction (MI)

Interventions
Not provided at time of registration

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Reinfarction, readmission, death

Secondary outcome measures

Not provided at time of registration

Overall study start date
01/10/1999

Completion date
01/12/2000

Eligibility

Key inclusion criteria
Post menopausal women (amenorrhoea for more than 12 months oestrogen deficiency symptoms) or more than 55 years, more than 48 hours and less than 7 days after the onset of acute Myocardial Infarction (MI) (Creatine Kinase [CK] twice upper limit or CKMB above the threshold considered diagnostic for myocardial damage in that centre) plus one of the two additional following criteria:
1. Admission for symptoms of acute myocardial ischaemia
2. Changes on the electrocardiogram supportive of a diagnosis of acute MI, provision of written informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
125

Key exclusion criteria
1. Unconfirmed MI
2. Use of HRT currently or previous 12 months, patients for whom clear indications for, of contraindications to, long term HRT
3. Increased risk of thromboembolism
4. Prior history of DVT or PE
5. BMI more than 32
6. Prolonged immobility
7. Known breast or endometrial cancer
8. Post-menopausal bleeding that has not been adequately investigated
9. Presence of non-cardiac condition influencing survival
10. Anticipated inability of the patient to comply with the study procedures

Date of first enrolment
01/10/1999

Date of final enrolment
01/12/2000

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Clinical Trials & Evaluation Unit
London
United Kingdom
SW3 6NP

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 (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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2006		Yes	No