ISRCTN22651289 https://doi.org/10.1186/ISRCTN22651289

Cardiovascular risk factors in post menopausal woman: The effect of mode of delivery of hormone replacement therapy (HRT)

Submission date 23/01/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 23/01/2004	**Overall study status** Completed	
Last Edited 21/12/2009	**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

N/A

Study information

Scientific Title

Study objectives
To establish differences, if any, in alteration in cardiovascular risk factors with HRT in post menopausal women according to route of administration of HRT, oral, transdermal and implant, using first oestrogen alone then oestrogen plus norethisterone, or testosterone for implant. There is increasing use of HRT by post menopausal women. Observational epidemiological studies in the United States but no randomised controlled trials of HRT have been carried out in the primary practice setting. Previous studies of cardiovascular risk factors have shown a variety of responses according to type of progestagen and oral or topical administration. None has examined the effect of route using identical progestagen.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised open label controlled parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Hypertension, menstrual disorders and hormone replacement therapy (HRT)

Interventions
Menopausal status was confirmed and women were randomised to one of three treatment groups or acted as controls. The treatment regimes were two oral groups, with cyclical or continuous progestagen, and one transdermal regime with cyclical progestagen. The group who had had a hysterectomy received HRT by implant. Each regime lasted six months: for the first 3 months, oestradiol unopposed was given by each route; for the second three months, norethisterone was added as the progestagen, orally and transdermally as appropriate.

Measurements: Blood samples
1. fasting glucose
2. insulin
3. total cholesterol
4. high-density lipoprotein (HDL) cholesterol
5. low-density lipoprotein (LDL) cholesterol and triglycerides
6. lipoprotein (a)
7. follicular stimulating hormone
8. lutenising hormone
9. oestradiol
10. factor VII
11. fibrinogen
12. plasmin antiplasmin
13. thrombin anti thrombin
14. Von willebrand factors
15. E-selectin

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Oestradiol, norethisterone, testosterone

Primary outcome measure
1. Response to HRT
2. Anthropometric measurements
3. Cardiovascular Risk Factors
4. Blood pressure
5. Lipoproteins
6. Glucose and insulin
7. Clotting variables
8. Arterial wall factors

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/02/1995

Completion date
13/03/2000

Eligibility

Key inclusion criteria
Women aged 50 - 65 years from lists in general practices local to the Charing Cross Hospital Lipid Clinic in West London.

Participant type(s)
Patient

Age group
Other

Sex
Female

Target number of participants
260 recruited (intervention group: 160, control group: 100); 161 completed (intervention group: 78, control group: 83); seperate implant group 34

Key exclusion criteria
Women with liver, renal or endocrine abnormalities were excluded, as were those on lipid altering medication.

Date of first enrolment
01/02/1995

Date of final enrolment
13/03/2000

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Cardiovascular Medicine
London
United Kingdom
W6 8RF

Sponsor information

Organisation
Record Provided by the NHS R&D 'Time-Limited' National Programme Register - Department of Health (UK)

Sponsor details
The Department of Health
Richmond House

79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
NHS Cardiovascular Disease and Stroke National Research and Development Programme (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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2000		Yes	No