ISRCTN54277211 https://doi.org/10.1186/ISRCTN54277211

MEN-Study: A randomized cross-over study on the effects of the skin patch and the vaginal ring versus a levonorgestrel containing oral contraceptive on the anticoagulations pathways

Submission date
27/01/2006

Recruitment status
No longer recruiting

Registration date
27/01/2006

Overall study status
Completed

Last Edited
19/08/2009

Condition category
Pregnancy and Childbirth

[_] Prospectively registered

[_] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Bea Hiemstra

Contact details
Leiden University Medical Center Department of Gynaecology
P.O. Box 9600
Leiden
Netherlands
2300 RC
+31 (0)71 5262871
B.Hiemstra@lumc.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Acronym
MEN-Study (Microgynon 30-EVRA-Nuvaring Study)

Study objectives
The effect on Activated Protein C (APC)-resistance of the skin patch and the vaginal ring contraceptives, containing third generation gestagens, is significantly increased in comparison with oral contraceptives, containing second generation gestagens.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from local medical ethics committee

Study design
Randomised open label active controlled crossover group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Other

Participant information sheet

Health condition(s) or problem(s) studied
Femal contraception, healthy person

Interventions
Skin patch and the vaginal ring versus a levonorgestrel containing oral contraceptive

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
APC-resistance

Secondary outcome measures
Other coagulation factors

Overall study start date
01/01/2005

Completion date
31/12/2006

Eligibility

Key inclusion criteria
Healthy female volunteers from 18-45 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
45 Years

Sex
Female

Target number of participants
20

Key exclusion criteria
1. Underage
2. Contra-indication for use of the contraceptive ring, skin patch or oral contraceptives, as termed by World Health Organization (WHO), Northen Virginia Oncology Group (NVOG) and the Dutch General Practitioners Society (Nederlands Huisartsen Genootschap [NHG])
3. Use of hormonal contraception or hormonal substitution therapy 2 months before inclusion
4. Pregnancy 3 months before inclusion or during the study
5. Use of medication with effect on the blood coagulation
6. Chronic or acute diseases
7. Lupus anticoagulans

Date of first enrolment
01/01/2005

Date of final enrolment
31/12/2006

Locations

Countries of recruitment
Netherlands

Study participating centre
Leiden University Medical Center Department of Gynaecology
Leiden
Netherlands
2300 RC

Sponsor information

Organisation
Leiden University Medical Centre (LUMC) (Netherlands)

Sponsor details
Department of Gynaecology
P.O. Box 9600
Leiden
Netherlands
2300 RC

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/027bh9e22

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Leiden University Medical Centre (LUMC), Department of Gynaecology (Netherlands)

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	01/09/2009		Yes	No