

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	<input type="checkbox"/> Prospectively registered
Registration date 27/01/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 19/08/2009	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

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

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), Northern 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