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Neonatal uterine bleeding as a precursor to adult life endometriosis

Submission date
03/11/2016

Recruitment status
No longer recruiting

Registration date
02/01/2017

Overall study status
Completed

Last Edited
29/12/2016

Condition category
Pregnancy and Childbirth

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Neonatal uterine bleeding (NUB) is a condition in which there is a small amount of bleeding or spotting from the vagina of newborn baby girls. It occurs in around 5% of all baby girls and usually happens during the first 2-3 days of life. Endometriosis is a common condition where small pieces of the womb lining (the endometrium) are found in different areas of the body, such as in the ovaries or in the bladder. The cause of endometriosis is still unknown and even after a century of intensive research it is still difficult to diagnose. The aim of this study is to collected routine medical data in order to find out if there is a link between NUB and the development of endometriosis in adulthood and if endometriosis is inherited.

Who can participate?
All female patients seeking advice for an infertility problem at a participating centre.

What does the study involve?
After agreeing to take part, participants complete a number of questionnaires in order to collect information about their health and personal information. The results of these questionnaires are then cross-checked with medical records which are reviewed to find out if there is a link between NUB and endometriosis formation in adulthood, as well as to see if endometriosis is inherited.

What are the possible benefits and risks of participating?
There are no direct benefits or risks involved with participating.

Where is the study run from?
1. St. George's Med School, Nicosia University and Aretaeio Hospital (Cyprus)
2. LIFE Expert Centre, Service de Gynécologie-Obstétrique CHR de la Citadelle and Ziekenhuis Oost-Limburg a.v. (Belgium)
3. 1st Dept Obstetrics and Gynecology Aristotle University of Thessaloniki (Greece)
4. University of Federico II, S.I.S.Me.R. srl (Italy)
5. IVI Valencia (Spain)
6. Maribor University Hospital (Slovenia)
7. Chinese University of Hong Kong (China)
8. Hôpital NATECIA and Chirurgie Gynécologique (France)

9. University Hospital of Obstetrics and Gynecology Elena Doamna (Romania)
10. Reproductive Clinic of Zurab Sabakhtarashvili (Georgia)
11. Malinov Clinic (Bulgaria)

When is the study starting and how long is it expected to run for?
June 2016 to September 2018

Who is funding the study?
European Academy of Gynaecological Surgery (Cyprus)

Who is the main contact?
Professor Vasilios Tanos
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Multicenter study on neonatal uterine bleeding (NUB) as a precursor in adult endometriosis

Acronym
NUB

Study objectives
The aim of this study is to determine whether there is a relationship between neonatal uterine bleeding during the first days of life and endometriosis/adenomyosis development later in adolescence or adult life.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Prospective observational cross sectional study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Other

Study type(s)
Diagnostic

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Neonatal uterine bleeding (NUB)

Interventions
When participants attend their appointments in infertility clinic, as part of their routine care, demographic data, reason for the visit (main complaint), past health and drug history as well as family history (questionnaire 2) are recorded. General, gynaecological and ultrasound scan examinations follow. They are then approached by the study team and / or their gynaecologist asking them to participate in the study, explaining that their routine data collected, blood tests, imaging records and if any interventional procedures results will be used for statistical analysis in the study. Once they consent to take part in the study the research team will collect the data by completing the questionnaire. They will be patients at a different stage of their treatment process and the responsibility of the team and / or gynaecologist is to complete the questionnaire along the way of the treatment. The questionnaires will be reviewed once again upon their completion to reassure the correct and complete medical records. Each participant infertility centre will provide 50 -60 patients for the time period of 2 years. The hard copy recorded data will be then send to the European Academy of Gynaecological Surgery - Nicosia Branch, and will be saved in a medical data base. Statistical analysis will follow.

Intervention Type
Other

Primary outcome measure
Impact of neonatal uterine bleeding in endometriosis formation in adulthood will be measured through medical record review at endline.

Secondary outcome measures
Inheritance of endometriosis will be measured by reviewing results of the second questionnaire which examines the pregnancy and labour conditions of the patient's mother at endline.

Overall study start date
10/06/2016

Completion date
30/09/2018

Eligibility

Key inclusion criteria
All female patients seeking advice for an infertility problem

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
500

Key exclusion criteria
No exclusion criteria

Date of first enrolment
01/10/2016

Date of final enrolment
30/09/2017

Locations

Countries of recruitment
Belgium

Bulgaria

China

Cyprus

France

Georgia

Greece

Hong Kong

Italy

Portugal

Romania

Slovenia

Spain

Study participating centre
St. George's Med School, Nicosia University and Aretaeio Hospital
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-

Study participating centre
LIFE Expert Centre
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University of Federico II
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Study participating centre
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-

Study participating centre
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Study participating centre

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Study participating centre
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Sponsor information

Organisation
European Academy of Gynaecological Surgery

Sponsor details
Nicosia Branch
Aretaeio Hospital
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2024

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00cfkaw62

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
European Academy of Gynaecological Surgery

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
31/12/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Prof Vasilios Tanos (v.tanos@aretaeio.com) and Prof Stephan Gordts (stephan.gordts@lifeleuven.be or stephan.gordts@lifeexpertcentre.be)

IPD sharing plan summary
Available on request