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Diagnosis of uterine anomalies using the new classification of ESHRE/ESGE

Submission date
01/04/2018

Recruitment status
No longer recruiting

Registration date
14/06/2018

Overall study status
Completed

Last Edited
25/04/2019

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Congenital anomalies of the uterus (womb) are defects of uterus development and shape that occur during fetal life. Their prevalence is estimated to be 5%, but up to a quarter of women who have had miscarriages or preterm deliveries have such defects.
Uterine abnormalities are natural in some women, who do not know about it until they start trying for a pregnancy. Until then, they usually cause no problem at all.
Septate uterus is when the uterus is separated on the inside into two different halves by a septum (partition) of varying size and thickness, and is the most common of diagnosed anomalies. Thus there are two uterus cavities. It is thought that even a small septum may affect embryo implantation and early pregnancy as the divided structure is different compared to the normal uterus lining and cannot sustain implantation. The diagnosis is confirmed by imaging studies, such as hysterosalpingography (a type of xray) 2D or 3D ultrasonography (ultrasound scan) and Magnetic Resonance Imaging (MRI).
Most uterine abnormalities can be diagnosed by means of hysteroscopy/laparoscopy which are procedures using a narrow telescope with a light and camera at the end (called a hysteroscope) to examine the inside of the uterus. These help the doctor examine the uterine cavity and the outer shape of the uterus.
Hysteroscopy offers the advantage that the patient can be diagnosed and treated (removal of the septate) at the same time, but its disadvantage is that it is a surgical procedure.
This study aims to estimate the diagnostic accuracy of three-dimensional ultrasonography (3D US) compared to hysteroscopy/laparoscopy.

Who can participate?
Adult women of reproductive age with suspected uterine malformations

What does the study involve?
All participants have a medical interview and clinical examination, 2D and 3D ultrasound and surgical procedures (hysteroscopy and laparoscopy) to diagnose and classify any uterine abnormalities.

What are the possible benefits and risks of participating?
The direct benefit of participating in the study is that women and particularly symptomatic

women (with infertility, recurrent miscarriage) know exactly what their problem is and at the same time they can undergo the correction of the problem. Their participation in the study may result in information that will help others in the future.
There are no risks and side effects of the 3D ultrasound.

Where is the study run from?
Papageorgiou General Hospital (Greece)

When is the study starting and how long is it expected to run for?
January 2012 to March 2016

Who is funding the study?
Papageorgiou General Hospital (Greece)

Who is the main contact?
Dr Anna Kougioumtsidou (Scientific)

Contact information

Type(s)
Scientific

Contact name
Mrs Anna Kougioumtsidou

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
AUTH 5867/29.03.2012

Study information

Scientific Title
Three-dimensional ultrasound in the diagnosis and the classification of congenital uterine anomalies using the ESHRE/ESGE classification: A diagnostic accuracy study

Study objectives
To estimate the diagnostic accuracy of three-dimensional ultrasonography (3D US) compared with the gold standard of hysteroscopy / laparoscopy, in the investigation of uterine congenital anomalies using the ESHRE/ESGE classification of female genital tract congenital anomalies.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Committee of Bioethics and Deontology School of Medicine of the Faculty of Health Sciences of Aristotle University of Thessaloniki, 28/06/2013, ref: AUTH Protocol No 49

Study design
Prospective blind comparative cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Congenital uterine anomalies

Interventions
All participants have a medical interview and clinical examination, 2D US and 3D US to diagnose and classify any uterine malformations according to ESHRE/ESGE classification of congenital anomalies of female genital tract.
They also have hysteroscopy and laparoscopy to diagnose and classify any uterine malformations according to ESGE/ESHRE classification.
Results of both diagnoses are compared for accuracy.
The participants are not followed up after the end of these assessments.

Intervention Type
Procedure/Surgery

Primary outcome measure
The accuracy of 3D US for the diagnosis of congenital uterine anomalies is assessed by comparing these results to hysteroscopy and laparoscopy results

Secondary outcome measures
The accuracy of 3D US for diagnosis according to the type of uterine congenital malformation is assessed by comparing results to hysteroscopy and laparoscopy results

Overall study start date
01/01/2012

Completion date
30/03/2016

Eligibility

Key inclusion criteria
1. Women with suspected uterine malformations
2. A presumptive 2DUS diagnosis of any uterine anomaly
3. Reproductive age

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
64 women

Key exclusion criteria
1. Pre-pubertal adolescents
2. Pregnancy
3. Menopause
4. Any presence of uterine fibroids

Date of first enrolment
01/07/2013

Date of final enrolment
31/12/2015

Locations

Countries of recruitment
Greece

Study participating centre

Papageorgiou General Hospital
1st Department of Obstetrics and Gynecology
Aristotle University of Thessaloniki
Thessaloniki
Greece
56403

Sponsor information

Organisation
Papageorgiou General Hospital

Sponsor details
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01663qy58

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Papageorgiou General Hospitall, Thessaloniki, Greece

Results and Publications

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

Intention to publish date

30/11/2018

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr. Anna Kougioumtsidou, akougioum@gmail.com

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		25/05/2018	25/04/2019	No	No