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Missed obstetric anal sphincter injury following vaginal delivery in primiparous women

Submission date
12/01/2016

Recruitment status
No longer recruiting

Registration date
10/02/2016

Overall study status
Completed

Last Edited
30/11/2017

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
After childbirth many women have a tear to the skin between the vagina and anus. When these tears also involve the underlying muscles controlling the anus they are referred to as OASIS (Obstetric Anal Sphincter Injury). OASIS is the most common cause of anal incontinence (gas, liquid or solid stool leakage) in women and often leads to great physical and social suffering and there is very little these patients can be offered. Evidence shows that by repairing these injuries directly and properly, later problems with anal incontinence can be reduced. Unfortunately, many injuries are missed at the obstetric ward, since the only examination following childbirth is an inspection of the vagina and perineum and a digital anal examination. Because of the bleeding and swelling, damage to the muscles is hard to recognise. The reported prevalence of OASIS ranges widely from about 2 to 25 %. In primiparous women (giving birth for the first time), clinical injury is reported in about 6 %. By adding endoanal ultrasound to the standard clinical examination an additional prevalence of occult injuries (no clinically evident anal sphincter tear) has been reported up to as high as 29%. In this study, the three-dimensional ultrasound (3-D EAS) will be used to investigate how many OASIS that are actually missed with the clinical routine of today and to assess the prevalence in primiparous women with vaginal delivery. 3-D EAS is the gold standard for evaluating the anal sphincter muscles. It is routinely used in departments specialising in pelvic floor disorders but not in obstetric care.

Who can participate?
Women giving birth for the first time at Östersunds Hospital.

What does the study involve?
After a participant has given birth, the midwife does the routine clinical examination and fill in the findings in a study protocol. She or he then performs the 3-D EAS recording. The recording only takes about a minute and is not painful. Each participant then comes back to the hospital 12 weeks after delivery for a new 3-D EAS examination to make sure no injuries are missed due to bleeding and swelling. The recordings are analysed by specialists to calculate the prevalence and a comparison made between the clinical findings and the 3-D EAS findings to see how many OASIS are actually missed with today's routines.

What are the possible benefits and risks of participating?
Taking part in the study is voluntary and a written consent will be obtained from all women. There are no risks with taking part and if we find large injuries on the recording we will break the code and contact the obstetricians. This will benefit the women taking part in the study.

Where is the study run from?
Östersunds Hospital (Sweden)

When is the study starting and how long is it expected to run for?
February 2015 to March 2018

Who is funding the study?
Östersund Hospital (Sweden)

Who is the main contact?
Dr Pär Nordin

Contact information

Type(s)
Scientific

Contact name
Dr Pär Nordin

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Prevalence and missed obstetric anal sphincter injury following vaginal delivery in primiparous women: a single center interventional study

Study objectives

Current study hypothesis as of 30/11/2017:
The hypothesis is that the prevalence is markedly higher than reported and the number of missed or undiagnosed obstetric anal sphincter injuries (OASIS) is high with the clinical examination routine of today.

Previous study hypothesis:
The hypothesis is that the number of missed or undiagnosed obstetric anal sphincter injuries (OASIS) is high with the clinical examination routine of today.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regional ethics committee, Umeå (Regionala etikprövningsnämnden i Umeå), 17/08/2015, ref: 2015-183-31M

Study design
A single center interventional study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Diagnostic

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

Health condition(s) or problem(s) studied
Obstetric anal sphincter injury (OASIS)

Interventions
Procedures
The 3-D EAS (3-D imaging of the external anal sphincter) will be performed using a Flex Focus 500 Ultrasound scanner (BK Medical, Denmark) with a 8838 axial endoscopic probe. All the midwives will receive information and training in how to perform the recording. The scanner will be pre-set and ready in the delivery ward. All the 3-D data will be stored and then reviewed by two-three independent examiners, all doctors specially trained in ultrasound and using the same 3-D viewing software (BK Medical).

Data collection and follow up
Prior to the delivery at their antenatal visit, about gestation week 18, data concerning the patient will be collected including age, ASA, medicines, body mass index and co-morbidity. Together with the written consent they will also fill in a short form with questions about earlier

surgery and/or problems with the anal sphincter and a validated wexner incontinence score form. The problem with discharge and other pregnancy-related events that could possibly affect the wexner score will at this time of the pregnancy probably not yet have arisen. The patients included in the study will after the delivery be examined by the mid-wife in charge who will inspect the vagina and make a digital anal examination. She or he will then fill in a prefabricated study protocol classifying the degree of the tear according to the WHO- classification (see definitions below) and then perform the blinded 3-D EAS-recording following step-by-step instructions. This will take place while the woman is still in supine position with legs in stirrups. The recordings will then be analysed by two independent and specially trained doctors using a specialised protocol including the Nordeval score and Stark score. After 12 weeks, a new 3D-EAS recording will be made to make sure no sphincter tears are missed because of oedema or bleeding, which may be present immediately post partum and make the image more difficult to analyse. A comparison will then be made of the number of OASIS found by clinical digital examination and the number identified with the 3-D EAS. Facts about the pregnancy, delivery and the new born will also be collected, including gestation week at delivery, type of anaesthesia, the use of instruments and/or episiotomy, induction of labour, augmentation of labour, weight and head-size of the infant, fetal presentation and APGAR score.

Definitions
Tears of the perineal area that occur at childbirth are usually classified into four degrees. A first-degree tear is defined as a laceration involving the perineal skin and vaginal mucous membrane but not the underlying fascia and muscle. A second-degree tear involves the fascia and muscles of the perineal body, but not the anal sphincter. A third-degree tear involves the anal sphincter /sphincters. A fourth-degree also involves the anal or rectal mucosa.
Third and fourth degree tears can also be referred to as OASIS.

Intervention Type
Procedure/Surgery

Primary outcome measure
Current primary outcome measures as of 30/11/2017:
To assess the prevalence of OASIS and compare the clinical examination with inspection and digital anal palpation to 3-D EAS, to examine the number of OASIS missed at clinical post-partum examination. Shortly after delivery the patients will be examined by the midwife or in eligible cases a doctor who will inspect the vagina and make a digital anal examination. Their findings will be documented in a study protocol classifying the degree of the tear according to the WHO-classification. The anal ultrasound will then be performed by an independent midwife clueless to the findings in the digital examination. The EAS finding will be saved in a data base for revision and classification within 2 weeks. After 12 weeks, a new 3D-EAS recording will be made by a mid-wife to make sure no sphincter tears are missed because of oedema or bleeding, which may be present immediately post partum and make the image more difficult to analyse.

Previous primary outcome measures:
To compare the clinical examination with inspection and digital anal palpation to 3-D EAS, to examine the number of OASIS missed at clinical post-partum examination. Shortly after delivery the patients will be examined by the midwife or in eligible cases a doctor who will inspect the vagina and make a digital anal examination. Their findings will be documented in a study protocol classifying the degree of the tear according to the WHO- classification. The anal ultrasound will then be performed by an independent midwife clueless to the findings in the digital examination. The EAS finding will be saved in a data base for revision and classification within 2 weeks. Ultrasound findings will be classified using the Starck scoring system for

sphincter defects. After 12 weeks, a new 3D-EAS recording will be made by a mid-wife to make sure no sphincter tears are missed because of oedema or bleeding, which may be present immediately post partum and make the image more difficult to analyse.

Secondary outcome measures
To examine risk factors for OASIS. Facts about the pregnancy, delivery and the new born will be collected, including gestation week at delivery, type of anaesthesia, delivery position, the use of instruments and/or episiotomy, induction of labour, augmentation of labour, weight and head-size of the infant, fetal presentation and APGAR score.

Overall study start date
01/02/2015

Completion date
30/03/2018

Eligibility

Key inclusion criteria
All primiparous women who deliver vaginally at Östersunds hospital during the study-period

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
800

Key exclusion criteria
1. Prior history of faecal incontinence
2. Anal sphincter surgery
3. Other known sphincter insufficiency

Date of first enrolment
31/08/2015

Date of final enrolment
01/04/2017

Locations

Countries of recruitment
Sweden

Study participating centre
Östersunds Hospital
Department of Surgery
Östersund
Sweden
S 83183

Sponsor information

Organisation
Östersund Hospital

Sponsor details
Department of Public Health and Clinical Medicine
Research Education and Development
Östersund
Sweden
S 831 83

Sponsor type
Research council

ROR
https://ror.org/027d2g669

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Östersund Hospital

Results and Publications

Publication and dissemination plan

Intention to publish date
01/06/2018

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Data sharing statement to be made available at a later date