ISRCTN11893931 https://doi.org/10.1186/ISRCTN11893931

Prevention of stillbirths from vasa praevia

Submission date
13/02/2019

Recruitment status
No longer recruiting

Registration date
14/02/2019

Overall study status
Completed

Last Edited
29/03/2021

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
Vasa praevia is a condition that occurs when blood vessels from the baby's umbilical cord or placenta are present in the membranes of the pregnancy sac, in close proximity to the opening of the womb (cervix). The presence of these blood vessels close to the cervix makes then susceptible to rupture when exposed to stretching or shearing stress from either rupture of pregnancy membranes or when there are labour contractions. The rupture of these vessels leads to loss of blood from the baby's blood circulation, which can lead to serious complications, such as stillbirth or problems due to lack of adequate oxygen supply to the baby's brain. This condition is not common and is reported to occur in about 1 in 2500 pregnancies. At present, there are no national recommendations to check for the presence of these blood vessels close to the cervix and the evidence from medical publications is that the lack of a diagnosis before birth can be associated with a high risk of complications such as stillbirth in up to 95% of such pregnancies. On the other hand, in pregnancies where there is knowledge of the presence of these blood vessels i.e. there is accurate prenatal diagnosis, then appropriate management can be associated with an improvement in survival in up to 95-100% of such pregnancies. There is also evidence from medical publications that an accurate diagnosis of vasa praevia is possible with use of ultrasound scanning. This would involve carrying out a transvaginal (internal) ultrasound scan along with use of Doppler (ultrasound test to check for blood vessels). The combination of these two methods can accurately diagnosis vasa praevia.
There is a currently a national drive to reduce stillbirths in the UK called the ‘Saving Babies Lives’ bundle. However, the screening and management of vasa praevia currently does not form a part of this national initiative to reduce stillbirths as there is uncertain evidence about effectiveness of such a policy. However, there is increasing evidence published recently which suggests that an effective strategy of screening and identification of such high-risk pregnancies with a clear evidence based policy of management could potentially prevent 10% of all stillbirths, which would be a very effective contribution to the national strategy of preventing 50% of stillbirths by 2025. Based on about 650,000 births annually in the UK, there would be an expected 2600 stillbirths and of these 260 would be secondary to vasa praevia.
There are specific risk factors such as those with velamentous cord insertion (attachment of the umbilical cord outside the placenta), those with a succenturiate or bilobed lobe (two separate lobes of the placenta as opposed to just one), multiple pregnancies, and those with attachment of the umbilical cord in the lower third of the womb. These factors would be associated with an increased risk of vasa praevia and such high-risk pregnancies can be offered further detailed ultrasound scanning using a combination of transvaginal ultrasound with use of colour Doppler

ultrasound. The combination of these is associated with a sensitivity (identification of affected pregnancies) of about 100% and screen positive rate (those classified to be at a risk of this condition) of less than 1%.
This current study aims to examine whether routine checking for location of the placenta and umbilical cord attachment during a routine scan at 12 and 20 weeks can effectively identify such high-risk pregnancies and once they are identified, whether a clear management plan is associated with preventing complications associated with vasa praevia.

Who can participate?
Pregnant women who delivered at the hospital during the study period

What does the study involve?
The researchers analyse data from all pregnancies in the study period to examine the prevalence, associated risk factors and pregnancy outcomes of vasa praevia and abnormal cord insertion. The data is taken from electronic databases of findings collected as part of routine clinical care.

What are the possible benefits and risks of participating?
This study does not involve direct patient contact or participation. However, the benefits of the study can potentially be that the results of the study may be generalizable to other patient populations with a potential reduction in stillbirths.

Where is the study run from?
Medway NHS Foundation Centre (UK)

When is the study starting and how long is it expected to run for?
December 2012 to June 2019

Who is funding the study?
Health Education England, Kent Surrey and Sussex (UK)

Who is the main contact?
Prof. Ranjit Akolekar
ranjit.akolekar@canterbury.ac.uk

Contact information

Type(s)
Scientific

Contact name
Prof Ranjit Akolekar

ORCID ID
http://orcid.org/0000-0001-7265-5442

Contact details
Institute of Medical Sciences,
Canterbury Christ Church University,
Rowan Williams Court, 30, Pembroke Court
Chatham

United Kingdom
ME4 4 UF
+44 (0)1634825110
ranjit.akolekar@canterbury.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
260634

Study information

Scientific Title
Preventing stillbirths: Impact of routine screening for vasa praevia

Study objectives
Vasa praevia is a condition that occurs when fetal umbilical or placental blood vessels are present in the amniotic membranes close to the internal cervical os unsupported by either the umbilical cord or placental tissue. The presence of these blood vessels close to the cervix, which may be either arterial or venous, makes then susceptible to rupture when exposed to shearing stress from either rupture of membranes or uterine contractions and cervical dilatation. The rupture of these vessels leads to blood loss from fetal circulation, which can lead to perinatal complications secondary to acute blood loss, such as fetal death or severe hypoxic morbidity. The lack of an antenatal diagnosis can be associated with risk of perinatal mortality in up to 95-97% of pregnancies whereas, in pregnancies where there is an antenatal diagnosis, the improvement in perinatal survival is about 93-100%.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 20/02/2019, London-Bromley Research Ethics Committee (Metropolitan Police Hayes Sports Club, The Warren, Croydon Road, BR2 7AL; 0207 1048027; nrescommittee.london-bromley@nhs.net), IRAS ID – 260634, REC ref: 19/LO/0413.

Study design
Retrospective cohort study

Primary study design
Observational

Secondary study design

Cohort study

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet
No patient information sheet as this study is a retrospective cohort study

Health condition(s) or problem(s) studied
Vasa praevia and abnormal umbilical cord insertion

Interventions
This is a retrospective cohort study undertaken at the Fetal Medicine Unit at a large maternity unit in United Kingdom. This unit routinely offers women an appointment at 11-13 weeks' gestation for dating of pregnancy, assessment of fetal anatomy and estimating individual risk for common chromosomal abnormalities based on combined screening. At this appointment, the protocol for scanning also includes documentation of placental location and cord insertion. The latter is documented as either velamentous, marginal or central cord insertion. Pregnancies with evidence of velamentous or marginal cord insertion in lower 1/3rd of uterus are followed up in the consultant clinic at 16 weeks for a review of findings and then again at 20-22 weeks' gestation to confirm the location of placenta and umbilical cord, to confirm or rule out the diagnosis of vasa praevia by undertaking a transvaginal ultrasound scan with colour Doppler. Pregnancies confirmed to have a diagnosis of vasa praevia are followed up in the high-risk clinic based on a specific protocol of follow-up and expectant management till 34-35 weeks' when elective cesarean delivery is planned, unless there are clinical concerns before this gestation. The trialists will undertake a retrospective data analysis of such data from all pregnancies in the study period to examine the prevalence, associated risk factors and pregnancy outcomes of vasa praevia and abnormal cord insertion. Data collected will be based on retrospective search of electronic databases which record antenatal, intrapartum and neonatal findings collected as part of routine clinical care.

Intervention Type
Other

Primary outcome measure
Stillbirth and perinatal mortality rate during the study period assessed in the standardised rate i. e. per 1,000 livebirths and as n (%). Data collected will be based on retrospective search of electronic databases. These will be compared between cases and controls and data will be presented as rates as well as odds ratios (95% confidence intervals)

Secondary outcome measures
1. The prevalence of vasa praevia, determined by the number of cases of vasa praevia during the study period divided by the total number of pregnancies delivered > 24 weeks during the study period
2. The maternal and pregnancy risk factors associated with vasa praevia. At every booking visit, maternal demographic factors (e.g. age, weight, height, racial origin, method of conception etc) are recorded for every pregnancy. Likewise, there are pregnancy risks factors such as medical conditions, pregnancy complications that are recorded for every pregnancy in the study period.

The researchers will compare these in pregnancies with vasa praevia to those without vasa praevia during the study period.

Overall study start date
01/12/2012

Completion date
01/06/2019

Eligibility

Key inclusion criteria
1. Singleton pregnancies which booked and delivered at our hospital during the study period
2. Delivered phenotypically normal neonates at ≥ 24 weeks' gestation

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
Retrospective cohort study over 5 years including all cases and control pregnancies. Based on the prevalence of vasa praevia reported in systematic reviews, we expect that our sample size of unselected retrospective cohort over the last 5 years should contain about 20 cases with vasa praevia.

Total final enrolment
26830

Key exclusion criteria
Multiple pregnancies, miscarriages, terminations of pregnancy, those with major fetal defects and those that were lost to follow-up

Date of first enrolment
01/01/2013

Date of final enrolment
01/01/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Medway NHS Foundation Centre
Fetal Medicine Unit,
Level 2, Green Zone, Windmill Road
Gillingham
United Kingdom
ME7 5NY

Sponsor information

Organisation
Medway NHS Foundation Trust

Sponsor details
Research and Innovation Department
Windmill Road
Gillingham
England
United Kingdom
ME7 5NY
+44 (0)1634 830000 ext 3129
hayley.beresford1@nhs.net

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01apxt611

Funder(s)

Funder type
Government

Funder Name
Health Education England, Kent Surrey and Sussex

Results and Publications

Publication and dissemination plan

The trialists are planning to publish the data in peer-review journals once the data analysis is complete.

Intention to publish date
01/04/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to the fact that the trialists have not obtained permission from patients for sharing their data.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/05/2020	29/03/2021	Yes	No