# Prevention of stillbirths from vasa praevia

Submission date	Recruitment status  No longer recruiting	Prospectively registered		
13/02/2019		☐ Protocol		
Registration date 14/02/2019	Overall study status Completed	Statistical analysis plan		
		[X] Results		
<b>Last Edited</b> 29/03/2021	Condition category Pregnancy and Childbirth	[] 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
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# Contact information

# Type(s)

Scientific

#### Contact name

Prof Ranjit Akolekar

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# Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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

### Study type(s)

Screening

## 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(s)

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)

# Key secondary outcome(s))

- 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.

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

## Healthy volunteers allowed

No

## Age group

Adult

### Sex

Female

#### 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

**United Kingdom** 

England

## 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

#### **ROR**

https://ror.org/01apxt611

# Funder(s)

## Funder type

Government

### Funder Name

Health Education England, Kent Surrey and Sussex

# **Results and Publications**

## 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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes