

# Screening for Group B Streptococcus bacteria in Malawian women going through childbirth to guide decisions on protective antibiotic prescription

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<b>Registration date</b> 09/06/2022	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 10/06/2022	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

The study is about a germ called Group B Streptococcus (GBS) which can make babies very sick. GBS is carried by many healthy women and does not usually cause any problems in the women. However, this bacterium can be passed from mother to baby during labour, and for some newborn babies, this germ can be dangerous, and can cause babies to become unwell. It is the commonest cause of serious infection and meningitis (inflammation around the brain) in babies up to 3 months old, and can even cause death and disability. Usually treatment of the germ is done before labor starts but because it is not routinely tested for in Malawi, doctors usually are not able to treat women earlier. More information is needed about this germ to help find the best way to prevent this disease in babies. The tests used to identify this germ also need to be improved. The aim of this study is to identify women who are infected with this germ and then treat them to help us determine if it is possible to treat women when they are in labor.

### Who can participate?

Women in active labor, at a gestational age greater than 34 weeks

### What does the study involve?

A swab will be taken from the vagina and rectum at admission and tested for GBS. If GBS positive, an antibiotic will be given to the woman before delivery and cord blood will be taken upon delivery of the baby.

### What are the possible benefits and risks of participating?

By taking part in the study the participant may help the researchers to try and reduce the number of babies that become unwell with GBS, and improve their understanding of when to administer antibiotics to best treat GBS infection. Also, participants carrying GBS will receive an antibiotic to reduce the chance of infecting their newborn babies. Taking the swab is painless. If the participant is GBS positive she will be offered an antibiotic (ampicillin) to get rid of the germ, and this will require an injection which may cause some mild discomfort. Some people are

allergic to the antibiotic, but treatment for this allergy is available in Queen Elizabeth Central Hospital for all mothers. The baby will feel no pain when blood is being taken from the cord.

Where is the study run from?

The study will be run at Queen Elizabeth Central Hospital in Blantyre, Malawi, with supportive guidance from Investigators based at Queens University, Belfast, Ireland.

When is the study starting and how long is it expected to run for?

March 2017 to December 2023

Who is funding the study?

The McClay Foundation (UK)

Who is the main contact?

Dr Chisomo Msefula

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## Contact information

### Type(s)

Principal investigator

### Contact name

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

P.04/21/3303

## Study information

**Scientific Title**

A feasibility study of intrapartum Group B Streptococcus testing using the loop-mediated isothermal amplification assay to guide antibiotic prophylaxis in Malawi

**Acronym**

GBS-S

**Study objectives**

A recent review of strategies to prevent Group B Streptococcus (GBS) disease in Africa (Nishihara et al, 2017) highlighted the difficulty of implementing either universal screening or risk-based intrapartum antibiotic prophylaxis (IAP) in resource-limited settings where culture facilities are not widely available. This project will assess whether the use of a rapid and accurate molecular diagnostic test to detect GBS during labour can identify at-risk pregnant women early enough for effective antibiotic prophylaxis to be used before delivery. Evaluating whether this strategy of test-directed IAP is feasible and can be implemented in a resource-limited setting will inform the development of clinical practice and guidelines in Malawi and beyond, bringing real clinical and health benefits. If successful, the work will lead to practical and high-impact clinical interventions to improve child health in Malawi, and potentially lead to substantial reductions in neonatal deaths.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Approved 16/06/2021, College of Medicine Research Ethics Committee (Kamuzu University of Health Sciences, Mahatma Gandhi Road, P/Bag 360, Chichiri, Blantyre, Malawi; +265 (0)1 871 911/ (0)1 877 245/(0)1 877 291; comrec@medcol.mw), ref: P.04/21/3303

**Study design**

Prospective clinical feasibility study

**Primary study design**

Observational

**Study type(s)**

Screening

**Health condition(s) or problem(s) studied**

Screening for Group B Streptococcus colonisation in pregnant women

**Interventions**

The study population includes women who present to the labor ward of Queen Elizabeth Central Hospital, Blantyre Malawi. Trained Research Midwife Nurses approach the women to provide information about the study and to seek consent for participation in the study.

A rectovaginal swab is collected from the consenting women and transferred to a room approximately 5 minutes away for testing of Group B Streptococcus using the HG GBS swab test (HiberGene Diagnostics Ltd, Dublin, Ireland). This is a commercially available molecular test with

CE-IVD approval for diagnostic testing in Europe, giving results in 30 - 45 minutes. It is a proven diagnostic test with excellent performance (sensitivity: 96.7%, specificity 97.7%, relative to an enriched culture method gold standard).

Women who test negative for GBS will receive standard of care, which may include antibiotic treatment if clinically indicated according to existing departmental guidelines. Women who test positive for GBS during labor will, in addition to standard of care, be offered intrapartum antibiotic prophylaxis according to existing practice in Malawi (slow intravenous injection of infusion of ampicillin). Immediately following delivery, samples of neonatal cord blood for determination of ampicillin concentration will be collected and stored for later analysis by reverse-phase high-performance liquid chromatography.

Women and babies from both groups (either negative or positive for GBS) will be followed up clinically 7 days later telephonically.

### **Intervention Type**

Other

### **Primary outcome(s)**

Colonisation with Group B Streptococcus measured using the loop-mediated isothermal amplification assay (LAMP) during labour at hospital admission

### **Key secondary outcome(s)**

1. Results turnaround time from sample collection (vaginal and rectal swabs) to the administration of ampicillin in those positive for Group B Streptococcus
2. Concentration of ampicillin in cord blood at delivery measured using high-performance liquid chromatography (HPLC) in GBS-positive women given ampicillin

### **Completion date**

31/12/2023

## **Eligibility**

### **Key inclusion criteria**

Pregnant women in active labour at a gestational age greater than 34 weeks ( $\geq 4$  cm dilated and regular contractions)

The researchers will also aim to identify and recruit women who present to the labour ward with premature rupture of membranes (PROM), but who are not yet in labour ( $< 4$  cm dilated). If recruited into the study, they will only be tested for GBS when labour begins ( $\geq 4$  cm dilated and regular contractions).

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

**Sex**

Female

**Key exclusion criteria**

1. Preterm labour with estimated gestation <34 weeks as the obstetric management highly variable in this group, including the administration of tocolytic drugs
2. Labour with an estimated fetal size of <2 kg (as a proxy for gestational age, which may not be reliable)
3. Presentation in labour with cervical dilation  $\geq 8$ cm as there is little likelihood of achieving testing and IAP before they deliver

**Date of first enrolment**

01/01/2021

**Date of final enrolment**

31/12/2022

**Locations****Countries of recruitment**

Malawi

**Study participating centre****Queen Elizabeth Central Hospital**

PO Box 95

Blantyre

Malawi

312200

**Study participating centre****Kamuzu University of Health Sciences**

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**Sponsor information****Organisation**

Queen's University Belfast

ROR

<https://ror.org/00hswnk62>

## Funder(s)

### Funder type

Charity

### Funder Name

The McClay Foundation

## Results and Publications

### Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study will be published as a supplement to the subsequent results publication

### IPD sharing plan summary

Published as a supplement to the results publication