

# Group B Streptococcal colonisation in the elderly

<b>Submission date</b> 06/01/2017	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 20/02/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 04/05/2021	<b>Condition category</b> Urological and Genital Diseases	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

The human body is home to trillions of tiny microorganisms (microbial colonization). The vagina is home to a range of different bacteria which help keep the vagina healthy by producing substances that stop unwanted organisms from growing. One of these bacteria is called Group B streptococcus (GBS). It has been found that vaginal GBS colonisation is found in between 20-30% of pregnant women, but little is known about the amount of women with GBS colonisation in older women (over 60 years old). The aim of this study therefore is to find out whether the colonisation rate in women over the age of 60 is different from that in pregnant women.

### Who can participate?

Women over 60 years old who are having a routine vaginal examination at the women outpatient clinic of the Bernese University Hospital

### What does the study involve?

Participants having an appointment at the women outpatient clinic of the Bernese University Hospital who meet the eligibility criteria are asked to complete a questionnaire about their background information and have a swab taken of their vagina during their routine examination. The swab is then taken to the laboratory and is used to find out what bacteria are present using standard techniques.

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

There are no direct benefits or risks involved to those participating.

### Where is the study run from?

Women Outpatient Clinic – Inselspital (Switzerland)

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

June 2016 to December 2019

### Who is funding the study?

Volunteer Academic Society of Basel (Switzerland)

Who is the main contact?  
Dr Parham Sendi  
parhams.sendi@ifik.unibe.ch

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Parham Sendi

**ORCID ID**  
<https://orcid.org/0000-0002-7347-6312>

**Contact details**  
Institute for Infectious Diseases  
Friedbühlstrasse 51  
Bern  
Switzerland  
3010  
+41 316 326 986  
parhams.sendi@ifik.unibe.ch

## Additional identifiers

**Protocol serial number**  
2016-01669

## Study information

**Scientific Title**  
Prevalence of Group B Streptococcal Vaginal Colonization in Elderly Women

**Acronym**  
GBS CITE STUDY

**Study objectives**  
**Primary objective**  
To calculate the prevalence of GBS colonization among elderly women. Elderly women in this study is defined as age of 60 years or older.

**Primary null hypothesis:**  
The colonization rate among elderly women is similar to that of pregnant women.

**Primary alternative hypothesis:**  
Elderly women have a higher colonization rate than pregnant women.

**Secondary objective**  
To identify host risk factors associated with GBS colonization.

Secondary hypothesis:

There is an association between GBS colonization and ethnicity, with comorbidities, with early onset of menstruation and multiple lifetime sexual partners.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Kantonale Ethikkommission Bern (KEK), 17/11/2016, ref: 2016-01669

### **Study design**

Single-centre observational cross sectional study

### **Primary study design**

Observational

### **Study type(s)**

Screening

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

Group B Streptococcal colonisation

### **Interventions**

For each patient there will be one assessment only. This assessment will take place during/in addition to routine medical visit. There are no specific or additional project visits.

First contact: Women having an appointment at the women outpatient clinic of the Bernese University Hospital will be screened for eligibility. Using a three step procedure, they will be asked whether they are willing to participate and written patient consent will be obtained.

At their routine gynaecological examination, a vaginal swab is collected. This investigation is part of routine procedure and will take less than one minute. The swab will be labelled with same code that is on the questionnaire. Participants are also asked to complete a questionnaire.

The questionnaire and the corresponding swab will be kept in an appropriate study bag. The study bag will be labelled with the same code. All study bags will be collected in a specific box and stored in the same room (i.e., working room with allowance of handling biological material [e.g., routine blood samples, urine, swabs, etc.]) during the day. The specific box will be labelled with the study name (GBS CITE study). A designated study nurse will empty the study box every evening.

The coded swab will be handed over to microbiology laboratory (Institute for Infectious Diseases, of the University of Bern). It will be screened via cultural methods for the presence of GBS. Upon detection of GBS, further characterization of the bacteria will be performed (e.g., serotyping, resistant patterns, etc.). The bacteria will be stored for potential further analyses. The study participants has the possibility to agree on the 'further use' of the bacteria in patient consent form. If the patient does not agree on the further use, the sample will be labelled accordingly. After the – by law on human research – requested storage time, the material will be destroyed.

The answers in the questionnaire will be typed into a data bank fulfilling requirements of the law on human research. The software SharePoint has been selected for this study. The data bank does not contain any information related to the patient (no name, no date of birth) but the CODE. The questionnaire in paper will be stored in a designed folder for the GBS CITE study.

**Intervention Type**

Biological/Vaccine

**Primary outcome(s)**

Evidence of GBS colonization is assessed using standard microbiological techniques on vaginal-rectal swabs taken at the study visit.

**Key secondary outcome(s)**

Presence of host factors associated with GBS colonization, including ethnicity, comorbidities, time point of menstruation and sexual history and behaviour are evaluated using a questionnaire designed for the purpose of this study at the study visit.

**Completion date**

31/12/2019

## Eligibility

**Key inclusion criteria**

1. Aged 60 years and over
2. Female
3. Undergoing a vaginal routine examination
4. Capable of understanding patient information

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Senior

**Sex**

Female

**Total final enrolment**

259

**Key exclusion criteria**

1. Inclusion criteria not fulfilled
2. Unable to read or understand study patient information document, either due to limitations in language skills or due to other reasons (e.g., mental impairment)
3. Patients with a legal guardian
4. Refusal to participate
5. Missing signed consent

**Date of first enrolment**

06/01/2017

**Date of final enrolment**

31/12/2017

## **Locations**

**Countries of recruitment**

Switzerland

**Study participating centre****Women Outpatient Clinic - Inselspital**

Universitätsklinik für Frauenheilkunde

Inselspital

Bern

Switzerland

3010

## **Sponsor information**

**Organisation**

University of Bern

**ROR**

<https://ror.org/02k7v4d05>

## **Funder(s)**

**Funder type**

Research organisation

**Funder Name**

Volunteer Academic Society of Basel (Freie Akademische Gesellschaft Basel)

## **Results and Publications**

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study are/will be available upon request from Parham Sendi ([parham.sendi@ifik.unibe.ch](mailto:parham.sendi@ifik.unibe.ch))

## IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		01/12/2021	04/05/2021	Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes