ISRCTN15468519 https://doi.org/10.1186/ISRCTN15468519

Group B Streptococcal colonisation in the elderly

Submission date	Recruitment status	[_] Prospectively registered
06/01/2017	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
20/02/2017	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
04/05/2021	Urological and Genital Diseases	

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 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)

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/12/2021	04/05/2021	Yes	No