

We are now inviting eligible individuals to participate in this study

## Oral Probiotic Supplementation in Pregnancy to Reduce Group B Streptococcus (GBS) Colonization

The OPSiP Study



What is GBS?

Why is GBS a concern?

**Study Question:**

**Can probiotics reduce the chance of being colonized with GBS?**



You may be eligible to participate

For more information, including on how to enrol, go to

[www.opsipstudy.com](http://www.opsipstudy.com)

email: [opsipstudy@bcchr.ca](mailto:opsipstudy@bcchr.ca)

or call the OPSiP line at 604-875-2000 ext. 4886



The probiotics and placebos have been donated by Chr Hansen, Denmark and Blis Technologies, New Zealand and are manufactured under Good Manufacturing Practices (GMP)

**You may be eligible to participate if you are**

- Healthy and pregnant with one baby
- Currently less than 25 weeks pregnant
- Over the age of 18
- Pre-registered at either St. Paul's Hospital or BC Women's Hospital (home birth included)
- Under the care of a regulated maternity care provider (Midwife, Obstetrician or Family Doctor)

**Some reasons you may not be able to participate include if you**

- Are unable to consent
- Are pregnant with more than one baby
- Plan to move outside of Vancouver before delivery
- Plan to use an oral (by mouth) or vaginal probiotic supplement or therapy in your pregnancy \*
- Are enrolled in another study or trial that involves the administration of a drug or other product

\* You can still eat and/or drink probiotic food products such as yogurt.



Questions?  
We are here for you!

You can contact us at 604-875-2000 ext. 4886 or email us at [opsipstudy@bcchr.ca](mailto:opsipstudy@bcchr.ca)

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## **What is GBS and why is it a concern in pregnancy?**

GBS (*Group B streptococcus*) is a type of bacteria that makes its home in parts of the human body (colonizes), including in the vagina.

In pregnancy up to 30% of individuals will test positive for GBS, meaning they do have it. 50% (half) of babies born to these individuals will get GBS bacteria on or in them (colonized). 1-2% of babies who get colonized by GBS may become sick from it and those babies face a life threatening illness.

GBS can be there one month and not the next, and the concern is it being passed to babies during labour. Most individuals go into labour at term (after 37 weeks) and so your care provider will offer you a test to see if you have GBS between 35 and 37 weeks of pregnancy.

If you do have GBS it will be recommended that you receive intravenous (IV) antibiotics during your labour and delivery. This reduces the chance of GBS being passed to your baby.

## **What are probiotics and are they safe to take while pregnant?**

Probiotics are bacteria that when taken in adequate amounts can be beneficial to one's health. Probiotics are considered safe in pregnancy, and may result in a number of benefits. These benefits can include lessening your chance of having a urinary tract or vaginal infection in pregnancy and improving your emotional health or mood. The most common negative side effect of probiotics is flatulence (or gas), and this most often stops once your body becomes used to the probiotic.

Health Canada has approved the use of the probiotics to be used in this study.

## **Why is this study important?**

Preventing GBS in the first place would reduce the need for IV antibiotics in labour for GBS and reduce the risk of GBS infection for newborns.

## **Risks and Benefits**

There are no known serious risks to you or your baby associated taking probiotics. The results from this study may benefit future pregnant individuals and their newborns.

Though participation in this study may be of no direct benefit to you, you might receive some benefit if you are randomly selected to take the probiotics.

Your care will continue to be provided to you by your primary maternity care provider. You will receive the same advice and recommendations from them as non-participants, including access to IV antibiotics in labour if you have GBS.

## **Participation: What can you expect?**

There is no cost for you to participate; the study supplements will be supplied to you for free. You will be randomly assigned (think of tossing a coin) to either the probiotic group or the placebo group. You, your care provider nor the researchers will know which you are taking.

**Participation is 100% voluntary and you may withdraw at any time from the study if you so choose**

## **By agreeing to participate you will:**

- **Meet with us in person twice, once at the beginning and once half way through**
- **Do two swabs of your mouth (we want to know if GBS lives there!)**
- **Take the study supplements (two capsules and one lozenge) daily from 25 weeks of pregnancy until you deliver your baby**
- **Do a total of three vaginal swabs (at intake, mid-point and one after 35 weeks) These are easy to do and you can do them yourself or have a clinician do them for you**
- **Complete three short questionnaires (at intake, mid-point and within 2-4 weeks after delivery).**

All of the study swabs will be provided to you and doing them does not cause any harm to you or your baby. They will provide us with valuable information on the potential effectiveness of the probiotics and additional information on GBS.

Participating in this study, even if you withdraw, will have no negative impact on the care you receive

For more details please go to the study website or contact one of the investigators.

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