

Clinical Study Of The Effect Of Gestational Weight Gain On Composition Of Gut Microbiome

Informed consent

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Dear mother-to-be:

We'd like to invite you for a clinical study: the effect of gestational weight gain on composition of gut microbiome. This study was conducted by Professor Ma Liangkun from Department of Obstetrics and Gynecology of Peking Union Medical College Hospital (PUMCH). The study proposal was reviewed by the medical ethics committee of PUMCH. Before you decide whether or not to participate in this study, please read the following carefully. You can discuss it with your family or friends, or ask your doctor for explanation.

The Purpose of This Study

Background: The gut microbiome regulates human physical conditions and would influence the occurrence and development of some diseases. It is suggested by recent epidemiological and clinical studies that the imbalance establishment of infant gut microbiome is closely related to the future development of childhood obesity, allergic diseases and autism.

Purpose: This study uses microbial gene sequencing technology to examine the microbiome structure in pregnant mother and the newborn, to determine the impact of gestational weight gain (GWG) on the distribution characteristics of maternal gut microbiota, oral microbiota and vaginal microbiota, and to reveal the impact of GWG on the infant gut microbiota.

Targeted participants: 550 pregnant women at 8-12 gestational week from PUMCH and other clinical centers.

The Proposal of This Study

The eligible participants will be asked to fill up a questionnaire upon voluntary agreement and signed written consent is obtained. After enrolment, biological samples (including oral, vaginal, fecal and blood samples) will be collected at first, second and third trimester, and 42 days after delivery. Fecal samples of the baby will be collected at 0-3 days after birth, 14 days, 42 days, 3 months, 6 months, 9 months and 12 months. Mothers are required to record their weight every day. Vaginal and blood samples will be collected by professional clinicians in hospital. Oral and fecal samples will be collected by participants at home.

We will provide more detailed flowchart for you to understand the study design. Your cooperation is much appreciated.

Your Obligation in This Study

As a participant, you will be required to provide your medical history and current physical condition truthfully. You are required to inform your clinician of any discomfort occurred during the study, to tell the research coordinate if you have been involved in or are involved in other research and to follow study procedures as described. You will not be allowed to participate in any other clinical study of any drug or medical device during the study period.

Risks and Adverse Reactions during The Study

You may feel inconvenient or uncomfortable with regular sampling. Blood and vaginal samples were collected by medical professionals. Fecal and oral samples collection is non-invasive and painless with no impact on the health of you or your baby. **If any adverse reactions occur, please contact your clinician immediately.**

Your samples will be coded with numeric digits instead of your name. Your personal information will not be disclosed to people other than the research team of this study. We will make every effort to protect the privacy of your personal medical data to the extent permitted by law.

Benefits of Joining This Study

No drug treatment was involved in this study. No additional risks or medical costs were added. The tests of biological samples collected (including blood, vaginal, oral and fecal samples) are free. You will be provided with a free scale for weight record. Research team will provide regular feedbacks on your baby's gut microbiome status. At the end of this study, you will receive a complete report of yourself and your baby's microbiome structures from early pregnancy to 1 year after birth.

Compensation for Adverse Reaction

There is no compensation involved in this study as the risk of any adverse reaction is minimal. There is no treatment involved in this study. Blood and vaginal samples were collected by medical professionals. Fecal and oral samples collection is non-invasive and painless with no impact on the health of you or your baby.

Do I have to join this study?

Participation is completely voluntary. You can refuse to participate in the study. You are entitled to withdraw from the study at any time. Participation or withdrawal will not affect your future treatment and medical benefits.

Biological Sample Assessment

The purpose of this study is to investigate the effect of gestational weight gain on mother and baby's gut microbiome and to set a GWG standard suitable for Chinese pregnant women. Furthermore, we'd like to study the correlation of early infant gut microbiome and future development of diseases. Hopefully we could find means for disease prevention and treatment through long term observation. Therefore, the your biological samples colle may be used in subsequent studies, i.e., secondary use.

If you sign this inform consent, you agree that your samples can be used for subsequent studies.

Contact Information

You are entitled to ask any questions regarding this study at any time. Your questions will be answered accordingly. Consultation contact (research team contact): 13121591988 (Dr Tian). You are entitle to ask questions regarding your benefits and risks related to this study. Consultation contact (Ethics committee contact): 69154494

Statement of Agreement

I have read the above introduction of this study and have the opportunity to discuss and raise questions with doctors about this study. All my questions were answered satisfactorily. I understand the possible risks and benefits of participating in this study. I understand that participation in this study is voluntary. I confirm that I have had sufficient time to consider and I understand:

- I can consult the doctors for more information regarding this study at any time
- I can withdraw from this study at any time without any discrimination. My medical benefits are not affected at any aspect

- If I need to take any other medication due to a change in my condition, I will consult my doctor beforehand or inform him/her truthfully afterwards.
- I agree that the drug regulatory authority, the ethics committee or the research organization's representative have the right to access to my research materials.
- I agree that the research team can use my samples for subsequent study .
- I will receive a copy of the signed and dated informed consent form

Lastly, I agree to participate in this study and promise to follow the doctor's instructions.

Participant's name: _____Signature: _____Date: _____

I confirm that I have explained to the participant the details of this study, including her rights and possible benefits and risks, and have given her a copy of the signed informed consent.