Informed Consent Form

Date:

Research Title

Effect of probiotic administration to breastfeeding mothers with very low birth weight neonates on some neonatal and maternal outcomes

Type of Research: Randomized Controlled Trial

Dear Madam,

You are cordially invited to participate in a study being conducted by Tabriz University of Medical Sciences. This study is overseen by the university's Regional Ethics Committee and is funded by the Vice-Chancellorship for Research and Technology. Before deciding on your participation, I will provide you with a brief explanation of the research, its purpose, and what it entails. Please take your time to carefully read the following information. If you require clarification, feel free to ask any questions. Do not feel pressured to decide to participate right away. Your participation in this research will involve no cost to you. Furthermore, if you are currently receiving any care from a specialist or midwife in public or private facilities, you will continue to receive your usual care throughout the study.

What is the purpose of this study and how will it be conducted?

Objective: The purpose of this study is to investigate the effect of probiotic administration on breastfeeding mothers with very low birth weight neonates on neonatal bilirubin levels, maternal depression, and some neonatal and maternal outcomes.

Methods: The participants will be randomly assigned to the probiotic group or the placebo group with a 1:1 allocation ratio. Probiotics or placebo will be administered in capsule form, to be taken orally over a period of six weeks. The researcher will provide the capsules daily. In cases where daily access is impractical, the supplements will be given weekly for you to consume at a special time of your convenience. You will be given a diary to record each intake and any potential side effects daily. In case of forgetting to take a capsule at the scheduled time, you should take it whenever you remember. If you miss a dose, please do not take two capsules a day, record the date in the diary, and return any remaining capsules to the researcher.

The information gathered will then be analyzed by the research team to determine the effect of the probiotic on selected neonatal and maternal outcomes, such as bilirubin levels, weight gain, and the occurrence of neonatal sepsis in infants and postpartum depression in mothers.

Why have I been chosen?

All women meeting the inclusion criteria for this study are eligible to participate if they wish. Based on these criteria, you are eligible to take part in this research.

What are the benefits of this research?

Studies suggest that probiotic supplementation may contribute to the well-being of both mothers and infants; preventing neonatal jaundice, and promoting better weight gain in infants, as well as improving mental health in mothers.

Are there any potential risks or side effects?

Previous research has established the safety of probiotics for breastfeeding mothers and very low birth weight infants. Nonetheless, we will closely monitor infants for any side effects or adverse reactions related to the intervention during their hospital stay. Should you or your infant experience any side effects or unwanted reactions, please report them in the diary. If discomfort persists, discontinue capsule intake and promptly contact the researcher for assistance. Management, follow-up, and compensation for any side effects will be provided at no cost.

Will my participation in this study remain confidential?

Your participation in this study, along with any information shared, will remain entirely confidential. Each participant will be assigned a unique identification number for the duration of the study, ensuring confidentiality. Data handling will adhere to Iranian data protection laws, guaranteeing the confidentiality of information.

What do I need to do if I want to participate?

If you choose to participate in this study, kindly complete the Informed Consent Form and return it to the researcher. Please retain a copy of this information sheet for your records. It is important to note that you are free to withdraw from the study at any time, without the need to provide a reason.

Your Role in the Research

Your role in this research entails coordinating with the researcher to receive and regularly take the probiotic supplement/placebo over a six-week period. Additionally, you will be required to complete the diary during the six weeks and complete study questionnaires at recruitment and 42-45 days post-delivery in the hospital. If attending the hospital is not feasible, 42-45-day-post-delivery questionnaires can be completed via telephone. Data collection will also involve daily observations of your child and the utilization of medical records for both you and your child. Moreover, blood samples taken from infants at recruitment, as well as on the 4th and 7th days post-intervention, will be used for both clinical and research purposes, including assessment of total serum bilirubin levels. Trained medical staff conduct the blood collection procedure with minimal blood volume and strict adherence to protocols to prevent complications.

For any urgent queries, you can contact the researcher 24 hours a day. Non-urgent questions can be addressed between 8 am and 11 pm.

If you have further inquiries or require additional information, please contact Maryam Ali-Kamali at Phone number: +98913…….. If you encounter any problems during your participation in this project, kindly contact the Ethics Committee specialist at the Vice-Chancellorship for Research and Technology at 33370119.

Thank you for dedicating your time to review this information sheet.

Please confirm the following:

- ☐ I have read and understood the participant information sheet dated [……..] for the aforementioned research study, and have had the opportunity to ask any questions.
- ☐ I understand that my participation in this research is voluntary.
- ☐ I am aware that I can withdraw from the study at any time without needing to provide a reason.
- ☐ I agree to participate in the above study/research.

Participant Name: Date: Signature:

Researcher Name: Date: Signature: