

INFORMED CONSENT FORM

Title of Research Project:

Effect of Bovine Lactoferrin on Seroconversion following polio vaccine administration in Children. A Randomized Control Trial

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Introduction

Assalamolikum, my name is _____. We are working with the Aga Khan University Karachi. We are doing a study in this hospital to measure the effect of supplementing Bovine Lactoferrin with breastfeeding on seroconversion of oral polio vaccine in children.

Background

Polio has been eradicated worldwide however in Pakistan the virus is still circulating and affecting young children. Oral polio vaccine protects against polio however some factors including illness, malnutrition and the capacity to fight against polio virus decreases its efficacy. Bovine Lactoferrin which is a safe and useful substance found in cow's milk helps in improving the children's gut to fight against micro-organisms and it also improves the capacity of the children to find against the germs. However, the effects of supplementing Bovine Lactoferrin with breastfeeding on strengthening the capacity of child to fight against polio are unknown.

Purpose of the Study:

In this study we want to know, whether supplementing Bovine Lactoferrin with breast milk improves child's capacity to convert the polio vaccine into more powerful agent to fight against polio compared to supplementing placebo with breast milk. There will be two groups in this study one group will receive Lactoferrin while the other group will receive Placebo (which is a inert substance which is designed to have no therapeutic value)

Eligibility:

We will include Mother and baby to participate in the study, Mothers will be recruited in their third trimester. Furthermore healthy neonates born to these mothers with no underlying complication will be recruited. Females with health issues and high risk pregnancies will be excluded from the study, whereas neonates born with congenital anomalies and severe illness will be excluded from the study

Procedure:

During your Antenatal care visit in your third trimester our team member will contact you to assess your eligibility to participate in this study. If you are eligible and willing to participate in the study the study team member will collect some demographic data from you.

Soon after the birth the study physician will examine the child and assess him/her. If the child is eligible the study physician will recruit him/her in one of the study groups. The decision of the allocation of group is based on chance, and your child can go in any of the group, i-e Bovine

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Lactoferrin or placebo. At the time of recruitment, only 3ml of cord blood/neonatal blood will be collected to assess polio antibodies at birth.

After recruitment the study team will dispense either Bovine Lactoferrin or placebo mixed with the expressed breast milk/formula milk/water depending upon which group your child is enrolled in. At the time of discharge, the study team will provide you the supplement for one week and will visit your house for assessing the compliance and wellbeing.

At 6 weeks, before the first dose of oral polio vaccine, a blood sample and stool sample of your child will be collected for which you will be asked to visit the health facility. Along with sampling, the general wellbeing of the child will also be assessed. At 7 and 8 weeks, stool sample of the child will be collected. Similarly, at the age of 10 weeks, before the second dose of oral polio vaccine, a blood sample of your child will be collected. At the age of 14 weeks, before the third dose of oral polio vaccine, stool sample of your child will be collected.

At the age of 18 weeks (4 weeks after the third dose of oral polio vaccine) a fourth dose of oral polio vaccine will be given to your child and before the dose a blood and stool sample will be collected. After this, stool samples will be collected at 19 and 20 weeks.

The blood samples will be collected by trained phlebotomists and only 3ml of blood will be collected for testing. These blood samples will be sent to Centre of Disease Control (CDC), Atlanta USA for testing of antibodies of polio and other vaccine preventable disease. For stool collection, our team will provide you stool containers and will collect the stool samples from your home. These stool containers will be brought to the field research Lab at AKUH and will be archived as per the protocol. The stool samples will be shipped to the National Institute of Health (NIH), Islamabad for further analysis related to the shedding of poliovirus.

All these tests will tell us if your child is protected against polio. Also, if you need medical assistance for your child during this time, you can contact our study team for further assistance. However, the use of bovine lactoferrin in children is safe without any reported side effects.

Benefits for the child

By participating, you will know about the general health of your child. Your child will also receive an extra dose of polio vaccine that will add to the child's prevention against polio disease. Your child will also get a free consultation by a physician in each visit/whenever required.

Risks and Discomforts:

There is a possible risk of discomfort or pain, and local bruising from the blood drawing of your child, whereas to minimize the risk, blood will be drawn by trained technicians using sterile needles and clean material. Your child may experience mild pain after having routine immunization. Some children may have redness, swelling, and bruising at the site. The child may receive pain medications if needed.

Confidentiality:

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The names and identity of the parents and their children will be kept private by the investigators and staff of the health facility. Only study personnel that need to keep contact with you and make sure that the samples are properly labeled, will have access to identifying information. Other information without names and identities will be shared with study investigators and a committee for watching over the safety of the study. The blood and stool samples collected from your child will be used only for the study related tests and will be safely disposed of on completion of the study as per the applicable national guidelines.

No data from this study will be presented, in published format or otherwise, in a manner which could identify you, your child or any individual participant.

Results

Results from your child's participation in this study will be communicated back to you once they become available.

Right to refuse or withdraw:

Your consent for your child to participate in this study is voluntary. You do not have to take part in this study if you do not wish to do so. You may decline participation now or later. If you refuse to participate, your child will not lose any access to medical services or other benefits provided by the government.

If you agree for your child to participate, you may provide a written consent. Or you may provide an oral consent and have a literate witness sign on your behalf.

Whom to contact:

You can ask any questions about this study or the consent form at any time. Also in case of any illness or your child needs any medical attention during the study period, you can contact the study physicians and supervisors on the following telephone numbers:

021-33100007 Ext. 7895 or 021-34829538 Ext 8030, 8050

Certificate of Consent

I have read and understood the consent form and I am willing to participate in this study voluntarily. I understand that I will receive a copy of consent form. I also understand that my participation in this study is voluntarily and in case of any personal irresponsibility or unlawful mistake my rights will remain restored. Further I understand that this form does not contain any thing which is against the law.

Name of participating child _____
Date of birth _____

Name of Child's parent _____
Relationship with the child _____
Signature of parent _____
Date / (dd/mm/yy) _____

If illiterate

Name of Independent Literate Witness _____
Signature of Witness _____
Date / / (dd/mm/yy) _____
Affix thumb impression of parent _____

Name of Study team member _____
Signature of Study team member _____
Date / / (dd/mm/yy) _____