Document:

Informed consent form- Parent/guardian

Protocol:

EFFECT OF A NUTRITIONAL SUPPORT SYSTEM (DIET, SUPPLEMENTS AND PROBIOTIC) FOR IMPROVING GROSS MOTOR FUNCTION IN CEREBRAL PALSY. AN EXPLORATORY RANDOMIZED CONTROLLED CLINICAL TRIAL

NCT number:

2014/03001

Date:

March 28, 2014

Universidad Anáhuac Norte / Teletón Children's Rehabilitation Center

Medical Research Unit

Mexico, D. F. to ____ of _____ of 20___

Informed consent form to participate in the project:

EFFECT OF A NUTRITIONAL SUPPORT SYSTEM (DIET, SUPPLEMENTS AND PROBIOTIC) FOR IMPROVING GROSS MOTOR FUNCTION IN CEREBRAL PALSY.

We requested your authorization, so that your child: _____, participated in a research project whose objective is to determine the effect of feeding, supplementation and probiotics on the stiffness of the muscles and the range of movement of children with moderate Cerebral Palsy taking into account the effect of nutritional status.

It is expected to improve the nutrition of children with Cerebral Palsy and improve absorption of nutrients at the intestinal level, their body will have the elements to improve the gross motor function, mobility and independence.

In case of agreeing to participate in the study, the child will be given the following:

a. Nutritional medical history: in this section you will be asked about aspects related to health, diet and habits of the child.
b. Clinical evaluation: the child will be assessed with the Gross Motor Function Measure (GMFM). This evaluation will be made at the beginning, seven-week and 13-week in the Teletón Children's Rehabilitation Center and is based on a clinical review with different activities to measure movement capacity.
c. Physical therapy: you will have to attend the Teletón Children's Rehabilitation Center twice a week to receive physical therapy for an hour and you should do the therapy daily in home.
d. Nutritional support: in the first consultation a nutritional support can be granted according to the group assigned, you should complete the food diaries that will be delivered every week in the consultation. You must be honest for the benefit of children and study.
e. Supplementation: the child can be supplemented or not according to the study group.

The duration of the study will be 13 weeks. In case the proposed treatment is beneficial, if your child does not have to receive it, we will provide it for the 13 weeks.

Before starting the study, a raffle will be held to assign your child in the follow-up group, conventional group or intervention group (can be in any of three). We hope that nutritional support will bring benefits to health. Previous studies by other researchers have shown that children with cerebral palsy tend to be malnourished and have problems from staying in good health. It is known that a malnourished child has poor results in their rehabilitation and development.

There may be some allergic effect or intolerance to any of the foods or supplements that is unpredictable until they are consumed, if this is the case, the intake should be suspended until it is assessed in the weekly consultation.

There could be unpredictable risks that are beyond the investigator's knowledge. If you present an adverse effect or require other type of attention with respect to the study, it will be provided attention that have always been offered.

The results obtained from this study are confidential and your participation has no cost and you will not receive payment for your participation. In addition, you and your child can leave the study at the time you decide without affecting the medical care you receive in the center. The study is supervised of Dr. Fernando Leal Martínez, Nutriologist Andrea Peña and Dr. Denise Franco (TEL: 57811904).

I, _____ have read and understood the above information and my questions have been answered in a satisfactory manner. I have been informed and I understand that the data obtained in the study can be published or disseminated for scientific purposes. I agree that my son participate in this research study. I will receive a signed and dated copy of this consent form.

_____ _____

Signature of participant or parent or guardian Date

_____ _____

Witness 1 Date

_____ _____

Witness 2 Date

This part must be completed by the Investigator (or his representative):

I have explained to Mr. (Mrs.) _____ the purposes of the investigation; I have explained to him (her) about the risks and benefits in this study. I have answered the questions and asked if they have any questions. I accept that I have read and know the corresponding regulations to carry out research with human beings and I am attached to it.

Once the question and answer session were concluded, the present document was signed.

_____ _____

Investigator's signature Date

Universidad Anáhuac Norte / Teletón Children's Rehabilitation Center