MEGA DONNA MEGA (MDM)
a randomized multicenter study designed to identify the optimal fatty acid supplement for premature babies

The study is now closed for inclusion

Background and aim

During the last three months of pregnancy there is vigorous growth and maturation of the brain and eyes of the fetus. Different fatty acids are important for this development to progress normally, and there are studies suggesting that the two polyunsaturated fatty acids, arachidonic acid (AA) and docosahexaenoic acid (DHA), are particularly important. They are normally transferred in large amounts from the mother to the fetus during the last months of pregnancy. With premature birth, the supply of fatty acids from the umbilical cord ceases and the premature baby is given its first nutrient supply directly into the bloodstream and later via breast milk or infant formula. The fatty acid supplements that can be administered directly into the blood contain too little AA and DHA for very premature babies. It is therefore important to find out whether early administration of the dietary supplement Formulaid ™ (which contains AA and DHA) reduces the risk of eye complications and improves children's growth and development.

What will the study involve?

After we have obtained the parents' consent, the babies will be randomly assigned to receive either only the fatty acid supplement normally used on the hospital ward when giving nutrients directly into the bloodstream (the control group) or the normal fatty acid supplement in combination with Formulaid ™ by mouth (the treatment group). Formulaid ™ is normally included in infant formula given to premature babies and is therefore approved for use in premature infants. In this study, Formulaid ™ will be given until the child reaches 40 weeks postmenstrual age.

In order to monitor the level of fatty acids in the infant and examine other factors that can affect growth and development, regular blood tests will be taken. The first samples are taken from umbilical cord blood on day 0, before starting the fatty acid supplement; further blood samples are taken on day 0, then 72 hours after birth, then 7 and 14 days after birth. Then blood samples are taken every two weeks until the baby reaches 40 weeks postmenstrual age. The samples are always taken in connection with the routine samples needed for the child's medical care, so no extra needle pricks are involved. The amount of blood taken is small and does not affect the baby. To investigate which fatty acids the baby ingests, the mother's breast milk is examined regularly. At postnatal day 1, when we place the tube in which your child receives the food in, we will take a small sample of gastric juice. We will also take a small sample of your child's lung secret if your child is on a ventilator. When the child is 3-5 days, 14 days, 28 days, and at discharge from the neonatal department, but not later than PMA 34 weeks, feces will be collected. At the same time four sterile cotton swabs will be rotated in the oral cavity of the infant. The feces and the cotton swabs will be sent for microbiological analyzes to study the early pattern of the normal intestinal. This is done to map the child´s early normal bacterial flora and if the flora is affected by the intake of Formulaid™. During this time the baby is given regular eye examinations and brain ultrasound according to normal clinical routine. When the baby is fully developed, an MRI scan of the brain is carried out. This examination is already carried out on many premature babies; it is safe for the baby and involves no pain or discomfort. The baby is awake during the scan, but may need a mild sedative. We also want to evaluate on this occasion how the nutrition we provide during early childhood is affecting body composition. Previous studies have shown that premature babies have a deviating body fat distribution versus full-grown children. Therefore we want to evaluate whether there is any difference in body composition and fat distribution between the children receiving the study drug (fatty acids) and the children who are not given the study drug. This examination is done with a PEA POD® that measures the child's body composition and it´s completely painless and takes about 2 minutes. At 2.5 and 6 years of age, the child's eyesight and mental and motor development are examined by pediatricians, ophthalmologists and psychologists according to clinical routine. Other information needed for the study are obtained from the mother's and the child's medical records.

Read more about the results:

https://jamanetwork.com/journals/jamapediatrics/fullarticle/2775874