

# Large clinical study on extremely preterm infants provides important knowledge about milk-based enrichment options

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Infants born extremely prematurely need to get enrichment as an addition to breast milk. But does it make any difference whether the enrichment is made from breast milk or cow's milk when it comes to the

risk of severe complications in children? This has been investigated by a large clinical study led from Linköping, Sweden.

Infants born extremely prematurely, between weeks 22 and 27 of pregnancy, are among the most vulnerable patients in health care. The risk of serious complications is very high. Almost one in four extremely [premature babies](#) die before the age of one.

There is strong research support for giving breast milk to these children rather than formula made from [cow's milk](#). It is known that cow's milk-based formula increases their risk of getting, for example, severe intestinal inflammation and sepsis (severe blood-borne infection).

"In Sweden, all extremely [preterm infants](#) receive breast milk from their mother or donated breast milk. Despite this, almost one in ten children get a severe inflammation of the intestine called necrotizing enterocolitis. It's one of the worst diseases you can have. At least three out of ten children die, and those who survive often have neurological problems afterward," says Thomas Abrahamsson, professor at Linköping University and senior physician at the neonatal department at the University Hospital in Linköping, who led the current study.

Historically, there have been very few studies on extremely preterm [infants](#) where treatments have been compared against each other. Therefore, there is a great need for [clinical studies](#) that can provide scientific support for how these children should be treated for better chances of survival and a good life.

In some countries, such as Sweden, infants are fed exclusively with either their mother's breast milk or donated breast milk. However, in order for extremely preterm infants to grow as well as possible, they need more nutrition than breast milk contains. This is why breast milk is supplemented with extra protein, so-called enrichment.

The enrichment has previously been made from cow's milk. However, there have been suspicions that cow's milk-based enrichment increases the risk of severe complications. Today, there is enrichment based on donated breast milk, which has begun to be used in health care in some places. The big question is whether it can reduce the risk of diseases in extremely preterm infants.

The current study, called N-Forte (the Nordic study on human milk fortification in extremely preterm infants), is the largest that has been carried out to seek answers to this question. The results have been eagerly awaited by pediatricians and others caring for these fragile infants.

"We concluded that it doesn't matter whether extremely preterm infants get enrichment made from cow's milk or made from donated breast milk," says Thomas Abrahamsson.

Although the study indicates that there was no difference between the two options, its results can be useful. The breast milk-based product is estimated to cost more than SEK 100,000 (approximately \$10,000) per child, which would be equivalent to around SEK 40 million if the product were to be used in Swedish health care.

"On the one hand, we're disappointed that we didn't find a positive effect of enrichment based on breast milk. On the other hand, it's a large and well-done study, and we can now say with great certainty that it doesn't have an effect on this patient group. This is also important knowledge so that we don't invest in expensive products that don't have the desired effect," says Thomas Abrahamsson.

The N-Forte study included 228 extremely preterm infants, randomly divided into two equally sized groups that received enrichment made from breast milk and cow's milk, respectively. The researchers examined

whether the two groups differed in the incidence of necrotizing enterocolitis, sepsis, and death.

Of the children treated with [breast milk](#)-based enrichment, 35.7% had these complications, while the corresponding proportion was 34.5% in the group receiving cow's milk-based enrichment, meaning there was no difference between the groups.

The results of the study are in line with a smaller study from Canada published in 2018. In that study, the researchers also did not see any difference between the two types of enrichment on necrotizing enterocolitis and severe sepsis.

The study was conducted at 24 neonatal departments in Sweden, and the research is [published](#) in *eClinicalMedicine*.

**More information:** Effect of human milk-based fortification in extremely preterm infants fed exclusively with breast milk: a randomized controlled trial, *eClinicalMedicine* (2024). [DOI: 10.1016/j.eclinm.2023.102375](#). [www.thelancet.com/journals/ecl... \(23\)00552-7/fulltext](#)

Provided by Linköping University

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