



# ELFIN Results Leaflet for Parents

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## ELFIN Results

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We are pleased to tell you that the results of the ELFIN trial of lactoferrin supplementation for very preterm infants have now been published. We would firstly like to thank you for helping us to make all of this possible, by allowing us to include your baby in the trial. Secondly, we'd like to summarise the results from the trial for you. If you want the results in greater detail they are available at [https://doi.org/10.1016/S0140-6736\(18\)32221-9](https://doi.org/10.1016/S0140-6736(18)32221-9) together with a commentary from an independent expert.

## The reasons for doing the trial

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Our main aim in doing the trial was to find a way to protect babies born very early from infection and necrotising enterocolitis (NEC). NEC is a very serious condition that affects the gut of very preterm babies (babies born more than 8 weeks early), where the tissue in the bowel becomes inflamed. Infection and NEC are important conditions to study because babies can get seriously ill, require surgery, and sadly, some babies will die from these conditions. Babies who survive can also experience problems with their growth and development. We still don't fully understand why these conditions affect some babies and not others, but we do know that the lining of the gut in some premature babies does not provide as good a defence to infection compared to more mature babies.

This study was designed to test whether or not giving lactoferrin to babies can help to protect them against infections and NEC. Lactoferrin is a naturally occurring protein processed from cow's milk (often used as a food supplement). A small study was previously carried out in Italy and, although the results were promising, we needed to find out more.

## What we did

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Between May 2014 and September 2017, we conducted a large study in neonatal units across the UK. More than 2200 very preterm babies took part to find out whether or not giving lactoferrin as a supplement is effective at preventing infections, NEC and other illnesses. It was hoped that lactoferrin could help to strengthen the wall of the babies' gut, making it less likely that bacteria would enter the body and cause disease. With your consent, your baby's doctors and nurses randomly (by chance) allocated your baby to receive either lactoferrin or sugar (sham treatment) mixed with milk once a day. This supplemented milk was given until your baby was no longer at a high risk of serious infections (the equivalent of 34 weeks' gestation). Your baby's nurses and doctors were not aware of whether each individual baby was receiving either lactoferrin or sugar. We collected details about all of the babies' progress and in particular we recorded all instances of infection or suspected NEC.

## What we found

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The number of babies who developed an infection or NEC was (statistically) the same in both groups:

- Infection occurred in 316 babies given lactoferrin and 334 babies given the sham treatment
- NEC occurred in 63 babies given lactoferrin and 56 babies given the sham treatment

The trial was big enough, and the rates of infection and NEC high enough, for us to be very confident that there is no benefit associated with lactoferrin in these babies. Importantly, we found no evidence of complications or side-effects associated with giving lactoferrin.

The results of the ELFIN trial do not support the routine use of lactoferrin for very preterm babies at the present time. We do trials when we are uncertain whether or not a treatment is helpful and it is very important that we do not use treatments that do not help. Despite not finding any benefit of lactoferrin, we have learned a great deal. The ELFIN trial was bigger and better than other lactoferrin trials and we now understand more about how infection and NEC might be prevented in the future. We are very grateful for your help with this important trial.

If you would prefer a paper copy of the results, please write to:

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This study was organised by the National Perinatal Epidemiology Unit (NPEU) CTU at the University of Oxford. The Unit is dedicated to improving the care provided to women and their families during pregnancy, childbirth and the period after birth, as well as the care provided to the newborn.