Enteral lactoferrin to prevent infection for very preterm infants: the ELFIN RCT

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Plain English summary

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Babies who are born ‘very prematurely’ (i.e. > 8 weeks early) need specialist hospital care on a neonatal unit. These babies can develop serious infections and illnesses during their stay in hospital. The risk of developing such infections is highest in the most premature infants.

This study was designed to test whether or not giving lactoferrin (The Tauta Cooperative Dairy Company Ltd, Morrinsville, New Zealand), a naturally occurring milk protein (often used as a food supplement), to babies can help to protect them against infections. A small study was previously carried out in Italy and, although the results were promising, we needed to find out more. A large study was undertaken in neonatal units across the UK. More than 2200 very premature babies took part to find out whether or not lactoferrin is effective at preventing infections and other illnesses. With consent from babies’ parents, clinicians randomly (by chance) allocated babies to receive either lactoferrin or sugar (sham treatment) mixed with milk once a day until they were no longer at a high risk of serious infections (the equivalent of 34 weeks’ gestation). The babies’ parents, nurses and doctors were not aware of whether each individual baby was receiving lactoferrin or sucrose (British Sugar, Peterborough, UK).

When all of the study data had been analysed, it was found that supplemental lactoferrin did not reduce the risk of infection or other serious illness or death, or affect the length of hospital stay, in very premature babies born > 8 weeks early. Because the study was large and used reliable methods, these results prove that lactoferrin supplementation does not have important benefits for very premature babies and that there is no need for any further research into the use of this treatment.
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