

Investigating the effectiveness of primary prevention strategies using hydrolysed milk formula and probiotic supplements to prevent allergic disease in high risk infants: pilot factorial trial

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Background: From birth to six months is the period of greatest immune maturation and lung growth and it represents a potentially critical time for interventions that aim to reduce the risk of developing allergic diseases. Evidence suggests that infants fed a probiotic supplement containing beneficial bacteria from birth may have increased numbers of beneficial bacteria and this in turn may lead to fewer infants developing allergic conditions. Also, exclusive feeding of extensively Hydrolysed Milk Formula (eHMF) in which the cow's milk protein which causes milk allergy has been broken down during the first four months of life has a possible additional protective effect in reducing infants risk of developing eczema when compared to infants fed normal cow's milk formula. This study aimed to investigate the effectiveness of probiotics and eHMF, used in isolation and in combination, in infants at high risk of developing allergic diseases such as eczema, hayfever and asthma in Scotland.

Aims: To test the feasibility of administering a placebo or probiotics to infants at high risk of allergic disease to breastfeeding and bottle-feeding mothers in Scotland, as well as administering an eHMF or normal formula to bottle-feeding mothers, and to compare the likely uptake and effectiveness of these interventions in a larger study.

Project outline/Methodology: Women were recruited from antenatal clinics, and by placing posters in healthcare and community settings. Infants were followed up at three and six months by a paediatric nurse. Determination of atopic disease was assessed by a physical exam by the paediatric nurse and skin and blood allergy tests.

Key results: 680 women were seen by a midwife in eight clinics over two months. Of these 680 women, 35 (5%) were ≥ 32 weeks and deemed at high risk according to our criteria. Out of these 35 women, 20 were interested in receiving further information about our study. Ten women signed the consent form. Four women remained in the study until the six month assessment (retention rate 40%). All four mothers that remained in the study found giving the probiotic intervention (breastfeeding mothers $n=3$) and probiotic and formula intervention ($n=1$) acceptable (100%).

Recruitment was no longer possible after approximately two months instead of the intended three months, because of issues raised about our study and the impact it may have on the UK Baby Friendly Initiative (UKBFI), which seeks to encourage women to exclusively breastfeed.

Conclusions: Although there are issues regarding the practicalities of recruitment and compliance uncovered in the course of undertaking this small pilot study, these can largely be resolved. Of greater concern is that it is currently not possible to deliver the intended follow-on larger study in Lothian (or most probably many other parts of Scotland) because of the midwifery staff having concerns that studies involving agents given by mouth, even in miniscule amounts as was the case in this study, may inadvertently compromise the message to exclusively breastfeed. Therefore, until this issue is resolved, it is not possible to undertake the planned follow-on larger trial in Scotland.

What does this study add to the field? It is possible to administer probiotics to newborn babies at high risk of allergic disease. Mothers who stayed in the study found that giving the probiotics to their baby, in addition to breastfeeding or formula feeding with eHMF was straightforward and they had no difficulties.

Implications for practice or policy: It is extremely important that methods of conducting research in a manner acceptable to the UKBFI are urgently identified. This pilot work has indicated that this or broadly comparable experimental studies cannot go ahead at present without the risk of running into severe difficulties.

Where to next? Future research should encompass qualitative research in order to determine a way around the midwifery blocking. Policy work should also be carried out in order to establish how the UKBFI can be pushed forward without blocking research in this way.

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