Dermatology Research in the West Midlands

BEEP Eczema Study (Barrier Enhancement for Eczema Prevention)

Website: [BEEP Study]

A randomised controlled trial to determine whether application of emollient from birth for a year, can prevent eczema in high risk children.

Queen’s Hospital, Burton is the only site in the West Midlands taking part in this study and the team has been very successful in recruiting. With a target of 86 patients randomised over 2 years, they have already consented 70 and randomised 38 since December 2014.

The primary objective of this study is to determine whether advising parents to apply emollient to their child’s skin daily for the first year of life in addition to best practice infant skin care advice can prevent or delay the onset of eczema in high-risk children, when compared with a control group who are given the best practice infant skin care advice only.

Barrier protection with emollients is a widely used first-line treatment for mild eczema and can have a dramatic steroid sparing effect when added to the treatment regimen for patients with moderate to severe disease. However, there are no studies looking at whether emollients can prevent eczema developing. If proven to be effective, this strategy could be an easy and low-cost approach to reduce the burden of eczema and potentially modify the development of associated allergic diseases such as food allergy and asthma. Women in their last trimester of pregnancy with a family history of either eczema, asthma or hay-fever will be invited to take part (babies born into families with eczema, asthma or hay-fever have a much higher risk of developing eczema). Families will then be randomly allocated to either the barrier enhancement group or the control group.

The barrier enhancement group will apply an emollient twice a day to the entire baby’s skin from birth to six months and will also use a soap substitute during this period. The control group will continue to treat their baby’s skin as they normally would. After six months, babies in both groups will be examined to see whether they have developed eczema. To avoid bias in the results, this will be done by a doctor or nurse who isn’t aware whether the family were in the barrier enhancement or the control group. A saliva sample will be taken from the baby to test for changes to the filaggrin gene, which has been implicated in the development of eczema.

Principal Investigator, Consultant Paediatrician Dr Mansoor Ahmed says: ‘We were able to achieve such good recruitment by utilising the established working relationship that our local research midwives already have with antenatal clinic staff. Having done similar projects in Obstetrics before, our research midwives were experienced in developing a data of potential participants by pre-screening the families attending the antenatal clinics. This experience helped us enormously with pre-screening potential families. We had several meetings (local PI and paediatric/midwifery research nurses) to brainstorm effective strategies in order to maximise successful recruitment. This included pre-screening families attending antenatal clinics, using posters in antenatal clinics and postnatal wards thus raising the awareness amongst users of antenatal clinic/postnatal wards. We also informed midwives, obstetric and paediatric medical staff working in the antenatal clinics, delivery suite and postnatal wards about this study with particular emphasis on the inclusion/exclusion criteria. This strategy enabled us to have a pool of ladies to approach about the study as soon as we were open for recruitment.'
‘We believe that having the research midwives and paediatric research nurses involved in the recruitment phase of this study has been essential part of our success at Burton. We ensured that one of the research nurse/midwife is rostered to attend antenatal clinic each day to maximise recruitment of potential families. Research midwives are located within the antenatal clinic and have a long standing relationship with the users of the clinic. One of the research midwives is still working as a midwife alongside her research role and therefore has been able to promote the study amongst colleagues on the wards too.

‘Thankfully, there were no major issues or obstacles identified locally. The midwifery team as a whole is very open and receptive to research and have helped identify potential participants. Research midwives and paediatric research nurses are well motivated. The local R&D department is also extremely supportive of research teams at the Trust. Moreover, regular meetings are held with local Principal Investigator (every 2 months) to discuss/tease out any difficulties or issues identified. Involving the midwife doing the NIPE checks has also helped to identify and approach any families that may have been missed through antenatal screening process.

‘So far we have found this study a very positive experience and we continue to encourage the midwifery team to refer potential participants. We have fed back to the team our high recruitment numbers via emails and thanked the team for their assistance regularly.

Dr Ahmed concludes: ‘Working alongside a highly motivated paediatric and midwifery research team locally has been a highly satisfactory experience. Regular research team meetings enable us to discuss this and other ongoing projects within the department at length. Achieving successful recruitment in this trial has been a triumph and all credit goes to a very successful relationship between paediatric/midwifery research teams alongside excellent support from midwifery staff. We feel proud to be the best recruiter so far and would like to continue our efforts in future too.

Clinical Research Midwife Stephanie Boswell says: ‘The help we have received from colleagues in ante-natal and post natal clinics and the imaging department has been invaluable. They have enabled us to approach likely participants face to face, which is the most successful method, and we couldn’t have done it without them. Ladies with eczema in the family are usually very keen to take part, and often they have hayfever and asthma in the family too. The study is not too onerous for the participants and that is definitely a plus – I would encourage other sites in the region to think about taking part.

‘We are also grateful to our R&D department for promoting research locally and continuing to support research midwives/nurses (backbone to successful recruitment in various multicentre trials).’

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