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Baby Skin Care Research Programme: Baby wipes study

Submission date
17/02/2010

Recruitment status
No longer recruiting

Registration date
13/05/2010

Overall study status
Completed

Last Edited
19/08/2013

Condition category
Skin and Connective Tissue Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
We carried out our study because we have little good quality evidence about the effects of using baby cleansing wipes on young babies skin. Recent professional guidance states that cotton wool and water should be use to cleanse a babys skin in the first month of life. However, other research that we have carried out informs us that mothers are confused about the best way to cleanse their babys skin, and find that cotton wool and water is not always efficient and can be inconvenient.
The goal of the study was to explore changes in babies skin during the first month of life (measured at day 1 and day 28 on the buttocks and thigh). Changes that were explored included skin hydration, evaporation levels of water through the skin, skin pH, inflammation or napkin rash and use of napkin rash cream. At day 28, a swab of the skin around the babys anal area was taken to assess levels of micro-organisms.

Who participated?
The study involved 280 mothers and their babies recruited during the first 48 hours after birth. All mothers were over 16 years of age, had pregnancies that lasted at least 37 weeks and babies who were well, and were using disposable napkins.

What did the study involve?
Mothers were provided with information about the study during their pregnancy. Within 48 hours of birth, mothers were invited to take part. Those who volunteered were randomly allocated to use either cotton wool and water or an optimally prepared baby cleansing wipe when cleansing their babys napkin area for one month. Mothers were provided with either the cotton wool or the baby cleansing wipes according to their random allocation. All mothers were also given the same disposable napkins for the month.
The babies skin was assessed at recruitment and later on day 28 during a home visit. Mothers also completed questionnaires about their personal background and methods of cleansing their babys skin during the study. Mothers completed a diary and recorded their cleansing practices each day. One month after the final skin assessments were made, mothers were telephoned and asked more questions about the condition of their babys skin and the skin cleansing practices used so that any other changes could be monitored.

What were the benefits and risks of participating?
There were no immediate direct benefits for those who took part. However, there will be benefits for future mothers as the results can be used to help mothers to make an informed decision about whether they will use an optimally prepared baby cleansing wipe or cotton wool and water when cleansing their babys skin, especially during napkin cleansing. There were no risks involved in taking part.

Where was the study run from?
The study was set up by The University of Manchester in collaboration with Central Manchester University Hospitals NHS Foundation Trust (UK).

When did the study start and how long did it run for?
The study started in January 2010 and ended in December 2010.

Who funded the study?
Johnson & Johnson (USA).

Who is the main contact?
Professor Tina Lavender
Tina.Lavender@manchester.ac.uk

Contact information

Type(s)
Scientific

Contact name
Prof Tina Lavender

Contact details
The University of Manchester
School of Nursing Midwifery & Social Work
Jean McFarlane Building
Oxford Road
Manchester
United Kingdom
M13 9PL
+44 (0)161 306 7744
Tina.Lavender@manchester.ac.uk

Additional identifiers

Protocol serial number
Protocol version 9

Study information

Scientific Title
Baby Skin Care Research Programme: Assessor-blinded randomised controlled trial comparing impregnated cleansing wipes with water in infants

Study objectives
The use of an optimally formulated cleansing wipe on the napkin area of newborn infants (greater than 1 month) has an equivalent effect on skin hydration when compared with using cotton wool and water (usual care).

Ethics approval required
Old ethics approval format

Ethics approval(s)
North West 11 Research Ethics Committee, Preston, approved on the 16th October 2009 (ref: 09 /H1016/118)

Study design
Randomised assessor-blinded controlled clinical trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Atopic eczema/atopic dermatitis

Interventions
Babies will be randomised to have their napkin area cleansed with the baby wipe or water and cotton wool. All participating mothers will be given a demonstration by a Health Care assistant or midwife who has been instructed on the appropriate advice and technique. All mothers will be advised to use the same nappy, which will be supplied by the researchers for the duration of the study. This will ensure similar absorbency, a factor likely to influence skin hydration. In both groups, parents will be advised not to use any nappy creams, other than that supplied by the research team.

The babies will be stratified according to risk of atopic eczema for analysis.

The treatment duration is 4 weeks and the follow-up is another 4 weeks after that so the babies are in the study for 8 weeks in all.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Change in measurements of hydration (buttocks and thigh). Skin hydration will be measured via conductance measurements using a skin surface hydrometer. A Corneometer® which is a well established method to determine reproducibly and accurately measure the hydration level of the skin surface, will be used. The measurements are non-invasive, using test sites on the baby's skin. Measurements will be made twice at each of two sites; measurements will be taken on the

buttocks and thigh. A baseline assessment will be made prior to maternal transfer into the community. A second assessment will be made at 4 weeks post-birth. The second measurement will be taken in the home. The exact locations where measurements are performed will be similar on all babies.

Key secondary outcome(s))
Measured at one day and 4 weeks:
1. Change in erythema measurements: instrumental assessment of skin erythema will be quantified via levels of oxyhaemoglobin in skin as measured by diffuse reflectance spectroscopy
2. Acceptability of intervention: women's views on smell, perception of cleanliness, perception of skin's moisture. This will be assessed using a structured questionnaire completed by the mother at both assessment and a diary completed from randomisation to 4 weeks post-natal. At 8 weeks post-natal, women will be invited to participate in a semi-structured telephone interview, to assess their views of their allocated cleansing routine, to determine their cleansing practice and record mother's perceptions of skin condition.
3. Nappy cream usage
4. Napkin dermatitis assessed at 4 weeks postnatal, by the midwife. We will use a Diaper Area Rash grading scale. The assessment will be made by the same research midwife to ensure data reliability. A set of reference photographs depicting the various levels of diaper rash will be used by the research midwives to ensure consistency in clinical assessment.
5. Rate of change in transepidermal water loss (TEWL) defined as the flux of condensed water diffusing through the skin
6. Change in skin surface pH (buttocks and thigh). Presence of skin contaminants and irritants on the peri-anal area (Coliform Bacteria and Candida species).

Completion date
31/12/2010

Eligibility

Key inclusion criteria
1. Participants with a pregnancy gestational age of 37 weeks and above, either sex
2. Using disposable nappies
3. Within the first 48 hours of birth

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Upper age limit
2 days

Sex
All

Key exclusion criteria
1. Admission to the neonatal unit
2. Phototherapy
3. Limb defects
4. Non-traumatic impairment of epidermal integrity, evidence of skin disorder at first visit - for the purposes of this study the following normal variations will not be considered skin disorders - erythema neonatorum/erythema toxicum
5. Milia
6. Women known to be carrying a baby with a chromosomal abnormality or other syndromic diagnosis
7. Women known to be having their baby adopted
8. Currently participating in another clinical trial
9. Maternal age less than 16 years
10. Women who are unable to communicate through learning difficulties will not be eligible to consent for their baby

Date of first enrolment
01/01/2010

Date of final enrolment
31/12/2010

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
The University of Manchester
Manchester
United Kingdom
M13 9PL

Sponsor information

Organisation
University of Manchester (UK)

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Industry

Funder Name
Johnson & Johnson (USA)

Alternative Name(s)
Johnson & Johnson, Johnson & Johnson Services, Inc., Johnson&Johnson, Johnson & Johnson Private Limited, , , J&J, JNJ

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2012		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes