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Baby Skin Care Trial: a study comparing an infant skin-cleansing product with water

Submission date	Recruitment status
17/03/2009	No longer recruiting
Registration date	**Overall study status**
26/05/2009	Completed
Last Edited	**Condition category**
21/12/2011	Skin and Connective Tissue Diseases

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Tina Lavender

Contact details
University of Manchester
Jean McFarlane Building
University Place
Oxford Road
Manchester
United Kingdom
M13 9PL
+44 (0)161 306 7744
tina.lavender@manchester.ac.uk

Additional identifiers

Protocol serial number
LWH0784

Study information

Scientific Title

Baby Skin Care Research Programme: a randomised, assessor-blinded controlled trial comparing an infant skin-cleansing product with water

Study objectives
Ammended 12/01/10:
Bathing healthy term babies using a baby wash product in the first 2 weeks following birth is not inferior to bathing babies using water alone.

Initial information at time of registration:
Infant skin cleansing with a product is superior to bathing with water only.

Please note that as of 12/01/10 this record has been updated. All updates can be found in the relevant field with the above update date. Please also note that the anticipated end date of this trial has been extended from 01/03/10 to 01/09/10, and that all outcomes will now be measured at 2 and 4 weeks, not 4 and 8.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Cheshire Research Ethics Committee, approved on 02/03/2009 (ref: 09/H1017/3)

Study design
Randomised assessor-blind single-centre trial

Primary study design
Interventional

Study type(s)
Prevention

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

Interventions
Babies will be randomised to be bathed in water only or bathe with the new baby wash product. All participating mothers will be given a demonstration bath by a health care assistant who has been instructed on the appropriate advice. Women will be given written instructions to take home. The intervention will last from birth until 8 weeks of age.

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

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)

Rate of change in trans-epidermal water loss (TEWL) measurement from the first bath until day 56 after birth. TEWL is defined as the flux of condensed water diffusing through the skin.

(Added 12/01/10):
Average of the TEWL measurements over three sites (arm, leg and abdomen) will be calculated.

Follow up will take place at 2 and 4 weeks following birth. This will include assessment of all primary and secondary outcome measures.

Key secondary outcome(s))
1. Acceptability of intervention The views of mothers and significant others on smell, perception of cleanliness, perception of skin's moisture, measured using a specifically designed questionnaire and diaries which have gained content validity by being informed by the earlier qualitative work
2. Skin surface pH
3. Measurement of hydration
4. Change in clinical observations (erythema, dryness and scaling, need for medical products/ attention)

Follow up will take place at 2 and 4 weeks following birth. This will include assessment of all primary and secondary outcome measures.

Completion date
01/09/2010

Eligibility

Key inclusion criteria
1. Screening phase:
1.1. Women carrying singleton pregnancies who are booked to give birth at the study hospital
2. Trial phase:
2.1. Babies (both males and females) born between 37 weeks and 41 weeks
2.2. In good general health (as determined by the investigator)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Neonate

Sex
All

Key exclusion criteria
1. Screening phase:
1.1. Women known to be carrying a baby with a chromosomal abnormality or other syndromic diagnosis
1.2. Women known to be having their baby adopted

2. Trial phase:
2.1. Admission to the neonatal unit
2.2. Phototherapy
2.3. Limb defects
2.4. 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
2.5. Milia
2.6. Maternal age <18

Date of first enrolment
09/03/2009

Date of final enrolment
01/09/2010

Locations

Countries of recruitment
United Kingdom

England

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

Sponsor information

Organisation
Liverpool Women's NHS Foundation Trust (UK)

ROR
https://ror.org/04q5r0746

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	13/05/2011		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes