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The use of oil in baby skincare trial

Submission date	Recruitment status	[X] Prospectively registered
22/08/2013	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
22/08/2013	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
16/01/2017	Pregnancy and Childbirth	

Plain English summary of protocol

Background and study aims
Many health professionals recommend the use of olive oil or sunflower oil to prevent or treat dry skin in full term, newborn babies. Other health professionals advise parents not to use any oil on their babys skin. There has been no research to consider which approach has any immediate or long-term effect on the way a baby's skin functions, and the advice given to parents can be conflicting. At present it is not known whether any oil is better or worse for a baby's skin than no oil. Dry skin is a normal physiological process for newborn babies, but parents want to treat it. There is also some evidence to suggest that products which are used on newborn skin may have an influence on the development of eczema (atopic dermatitis). The aim of this study is to explore what is the best way to find out whether olive oil, sunflower oil or no oil is best for a baby's skin.

Who can participate?
Babies born at or after 37 weeks of pregnancy

What does the study involve?
The babies are randomly allocated to one of three groups to use olive oil, sunflower oil or no oil for 28 days. Their skin is assessed to see if the oil causes any changes. The tests are carried out twice: once before the mother and baby leave the hospital after birth and then again after 28 days.

What are the possible benefits and risks of participating?
This study will help to develop the best way to find out which skincare treatment (olive oil, sunflower oil or no oil) is best, and will help to guide future advice for newborn baby skincare. The skin tests will not harm the baby.

Where is the study run from?
St Mary's Hospital (UK)

When is study starting and how long is it expected to run for?
Recruitment will start on 4th September 2013 and continue for up to one year.

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Mrs Alison Cooke
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Contact information

Type(s)
Scientific

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Mrs Alison Cooke

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
14926

Study information

Scientific Title
The use of Oil in Baby SkincaRE (OBSeRvE) trial: a pilot, assessor-blinded, randomised controlled trial to assess the impact of olive oil and sunflower oil on a term baby's skin barrier function

Acronym
OBSeRvE

Study objectives
The regular application of sunflower oil, when compared to no oil or olive oil, improves the skin barrier function of newborn term infants.

Ethics approval required
Old ethics approval format

Ethics approval(s)
First MREC approval date 19/07/2013, ref: 13/NW/0512

Study design
Randomised; Interventional; Design type: Process of Care

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: Reproductive Health and Childb, Generic Health Relevance and Cross Cutting Themes, Skin; Subtopic: Reproductive Health and Childb (all Subtopics), Generic Health Relevance (all Subtopics); Disease: Reproductive Health & Childbirth, Paediatrics

Interventions
1. Olive oil: Women in the intervention group will be asked to apply 4 drops of defined content oil twice daily to their baby on each of three sites: left forearm, left thigh and abdomen, for 28 days.
2. Sunflower oil: Women in the intervention group will be asked to apply 4 drops of defined content oil twice daily to their baby on each of three sites: left forearm, left thigh and abdomen, for 28 days

Follow Up Length: 1 month(s)

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Transepidermal water loss (TEWL); timepoint(s): baseline (within 48 hours of birth), follow up (28 days old)
2. Skin barrier function (change in spectral profile of lipid lamellae)

Secondary outcome measures
1. Skin surface hydration; timepoint(s): baseline (within 48 hours of birth), follow up (28 days old)
2. Skin surface pH; timepoint(s): baseline (within 48 hours of birth), follow up (28 days old)
3. Clinical observations; timepoint(s): baseline (within 48 hours of birth), follow up (28 days old)
4. Maternal satisfaction; timepoint(s): 28 days

Overall study start date
04/09/2013

Completion date
31/08/2014

Eligibility

Key inclusion criteria
Inclusion criteria for screening phase:
Women carrying singleton pregnancies who are booked to give birth at St Mary's Hospital, Manchester

Inclusion criteria for trial:
1. Newborn term infants (born on or after 37+0 weeks gestation) less than 48 hours old
2. In good health (determined by investigator)

Inclusion criteria for qualitative interviews:
Any parent with an infant taking part in the OBSeRvE pilot RCT who has consented to take part in the qualitative study, and is purposively selected for interview

Target Gender: Male & Female; Upper Age Limit 28 days ; Lower Age Limit 0 days

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
Planned Sample Size: 100; UK Sample Size: 100

Key exclusion criteria
Exclusion criteria for screening phase:
1. Women known to be carrying an infant with a chromosomal abnormality or other syndromic diagnosis
2. Women known to be having their infant placed in foster care or adopted
3. Women with multiple pregnancies
4. Maternal age of less than 16 years

Exclusion criteria for trial:
Women:
1. Maternal age of less than 16 years
2. Unable to communicate consent for their infant to take part in the trial due to learning difficulties

Infants:
1. Admission to neonatal unit

2. Phototherapy
3. Limb defects
4. Non-traumatic impairment of epidermal integrity defined as abnormal epidermis or dermis such as collodion baby or congenital ichthyosis
5. Any medical history that may prevent the participation in the study until study conclusion
6. Currently participating in another clinical trial
7. Evidence of active skin disease or disorder at first visit (for the purposes of this study the following normal variations will not be considered skin disorders: erythema neonatorum / erythema toxicum; milia)

Date of first enrolment
04/09/2013

Date of final enrolment
31/08/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Oxford Road
Manchester
United Kingdom
M13 9PL

Sponsor information

Organisation
University of Manchester (UK)

Sponsor details
Oxford Road
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Sponsor type
University/education

ROR

https://ror.org/027m9bs27

Funder(s)

Funder type
Government

Funder Name
NIHR Doctoral Research Fellowship (UK); Grant Codes: DRF-2012-05-160

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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	01/03/2016		Yes	No
HRA research summary			28/06/2023	No	No