

The use of oil in baby skincare trial

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

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 baby's 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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Additional identifiers

Protocol serial number
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

Primary study design
Interventional

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

Study type(s)

Other

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(s)

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)

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Neonate

Sex

All

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

United Kingdom

England

Study participating centre

Oxford Road

Manchester

United Kingdom

M13 9PL

Sponsor information

Organisation

University of Manchester (UK)

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

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

