ISRCTN00356649 https://doi.org/10.1186/ISRCTN00356649

Efficacy of petroleum jelly in the prevention of irritant diaper dermatitis

Submission date
08/10/2010

Recruitment status
No longer recruiting

Registration date
09/11/2010

Overall study status
Completed

Last Edited
09/11/2010

Condition category
Skin and Connective Tissue Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Study information

Scientific Title
A randomised controlled double blind trial with parallel groups of newborn children admitted to the neonatal unit randomised to petroleum jelly or usual care for the prevention of irritant diaper dermatitis

Study objectives
The use of petroleum jelly as a barrier method, easy to use and easy removal, high visibility in the area of skin that covers and low cost, can help to decrease the incidence of diaper

dermatitis, providing greater comfort to the child, reducing worry and anxiety of parents and in turn creating a greater degree of satisfaction among nursing staff at the unit.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Clinical Research Ethics Committee of Guipuzcoa Health Area approved on the 21st June 2010

Primary study design
Interventional

Study design
Randomised controlled double blind parallel group trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Irritant dermatitis

Interventions
Experimental group:
Application of petroleum jelly to the infants after each diaper change. The amount of product to use is between 1 - 2 ml (depending on the weight of the child), the size of a hazelnut and will run for the perianal area and perineum.

Control group:
Usual care. Diaper changes as usual (like the other group), but not application of petroleum jelly.

Both interventions and follow up will end at discharge.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Petroleum jelly

Primary outcome(s)
Occurrence and time of diaper dermatitits using the Lane and Drost Scale. The existence of diaper dermatitis will be assessed every day during medical ward round.

Key secondary outcome(s)
No secondary outcome measures

Completion date
01/12/2011

Eligibility

Key inclusion criteria
1. Neonates admitted to the Neonatal Unit of the Hospital Donostia in the area of media care
2. Newborns greater than or equal to 1500 grams at birth
3. Infants whose stay in the unit is between 4 and 21 days
4. Both genders will be included during neonatal period from 0 to 1 month

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Neonate

Sex
All

Key exclusion criteria
1. Newborn from the Neonatal Intensive Care
2. Newborn with diaper dermatitis in the admission
3. Neonate admitted that less than 4 days
4. A newborn with pathology or alterations in skin integrity
5. Newborn under insolation
6. Newborn carrier catheterisation
7. Newborn transferred to intensive care because of worsening

Date of first enrolment
01/12/2010

Date of final enrolment
01/12/2011

Locations

Countries of recruitment
Spain

Study participating centre
Clinical Epiedemiology Unit.
San Sebastian
Spain
20014

Sponsor information

Organisation
Hospital Donostia (Osakidetza) (Spain)

ROR
https://ror.org/04fkwzm96

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Hospital Donostia (Osakidetza) (Spain)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration