

Efficacy of petroleum jelly in the prevention of irritant diaper dermatitis

Submission date 08/10/2010	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 09/11/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 09/11/2010	Condition category Skin and Connective Tissue Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Jose Ignacio Emparanza

Contact details
Clinical Epidemiology Unit.
Donostia Hospital
Pº Dr Beguristain 107-115
San Sebastian
Spain
20014

Additional identifiers

Protocol serial number
N/A

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

Study design

Randomised controlled double blind parallel group trial

Primary study design

Interventional

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 dermatitis 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 Epidemiology 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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes