

# Efficacy of petroleum jelly in the prevention of irritant diaper dermatitis

<b>Submission date</b> 08/10/2010	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 09/11/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 09/11/2010	<b>Condition category</b> 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**  
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20014

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

**Secondary identifying numbers**  
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

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Other

**Study type(s)**

Prevention

**Participant information sheet**

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

**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 measure**

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.

**Secondary outcome measures**

No secondary outcome measures

**Overall study start date**

01/12/2010

**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

**Age group**

Neonate

**Sex**

Both

**Target number of participants**

103

**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)

**Sponsor details**

Pº Doctor Beguiristain 107-115

San Sebastian

Spain

20014

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.osakidetza.euskadi.net>

**ROR**

<https://ror.org/04fkwm96>

## **Funder(s)**

**Funder type**

Hospital/treatment centre

**Funder Name**

Hospital Donostia (Osakidetza) (Spain)

**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