ISRCTN89579779 https://doi.org/10.1186/ISRCTN89579779

The use of Aquaphor to prevent transepidermal water loss and to maintain electrolyte balance in preterm newborn infants in the first week of life.

Submission date
30/09/2004

Recruitment status
No longer recruiting

Registration date
30/09/2004

Overall study status
Completed

Last Edited
10/03/2011

Condition category
Neonatal Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0060131640

Study information

Scientific Title

Study objectives
Will the use of an emollient (aquaphor) in the first week of life reduce transepidermal water loss (TEWL) in very preterm babies and improve their metabolic and electrolyte balance compared to infants not given the emollient treatment ?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Neonatal Diseases: Transepidermal water loss (TEWL)

Interventions
Standard care compared with emollient (aquaphor) therapy in addition to standard care.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)

aquaphor

Primary outcome measure
1. Fluid requirement in 1st week of life
2. Neonatal morbidity: electrolyte balance, metabolic balance, chronic lung disease, treated patent ductus arteriosus

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/11/2003

Completion date
31/12/2007

Eligibility

Key inclusion criteria
Not provided at time of registration

Participant type(s)
Patient

Age group
Neonate

Sex
Not Specified

Target number of participants
88 babies

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/11/2003

Date of final enrolment
31/12/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Neonatal Unit
London
United Kingdom
SW10 9NH

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Chelsea and Westminster Healthcare NHS Trust (UK)

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?
Abstract results	results			No	No