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A randomised controlled study to compare efficacy and safety of chlorhexidine powder versus dry care in umbilical cord care of the newborn

Submission date	Recruitment status	[_] Prospectively registered
06/09/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
05/10/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
10/09/2009	Pregnancy and Childbirth	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
Final version 16/04/2003

Study information

Scientific Title

Acronym
IPSS C 002

Study objectives
The primary objective of this trial is to show the superiority of chlorhexidine powder over a non-treated (dry care) control group regarding the separation time of the umbilical cord stump.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Umbilical cord care of the newborn

Interventions
Topical umbilical cord care with 1 g chlorhexidine powder or dry care with every diaper change (not less than 3 diaper changes per day) by the nurses and midwives in the nursery and by the parents at home for at least 3 days following cord detachment versus dry care of the umbilical cord.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Chlorhexidine powder

Primary outcome(s)
Cord separation time

Key secondary outcome(s)
1. Frequency of omphalitis (and their symptoms: erythema, oedema, tenderness, secretion)
2. Signs of ulceration, granulomas
3. Parents' acceptance of treatment and satisfaction with treatment
4. Adverse events, overall assessment of tolerability by the physician and the patient's parents

Completion date

31/12/2005

Eligibility

Key inclusion criteria
1. Healthy newborns on the first day of life
2. Gestational age: 37-42 weeks
3. Birth weight >2500 g
4. Informed consent given in a written form by both parents after being provided with detailed information about the nature, risks, and scope of the clinical trial as well as the expected desirable and adverse effects of the drug

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Neonate

Sex
All

Key exclusion criteria
1. Current participation in another clinical trial
2. Signs of clinically relevant illnesses (excluding physiological neonatal hyperbilirubinemia)
3. Evidence for HIV- or Hepatitis B/C-infection
4. Evidence for infection of the newborn (also expected antibiotic therapy)
5. Treatment of the subject with systemic antibiotics
6. Treatment of the umbilical cord with local antimicrobial regimen before randomization
7. Twins or triplets
8. Delivery at home
9. Legal incapacity and/or other circumstances rendering the subjects parents unable to understand the nature, scope and possible consequences of the study
10. Unreliability or lack of cooperation from the parents
11. Any other condition which, in the opinion of the investigator, would render the subject ineligible for the study

Date of first enrolment
01/10/2003

Date of final enrolment
31/12/2005

Locations

Countries of recruitment
Germany

Study participating centre
Childrens Hospital University of Leipzig
Leipzig
Germany
D-04103

Sponsor information

Organisation
Riemser AG (Germany)

ROR
https://ror.org/01a7r5j51

Funder(s)

Funder type
Industry

Funder Name
Riemser AG (Germany)

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	01/07/2009		Yes	No