ISRCTN63012285 https://doi.org/10.1186/ISRCTN63012285

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

**Submission date**
06/09/2005

**Recruitment status**
No longer recruiting

**Registration date**
05/10/2005

**Overall study status**
Completed

**Last Edited**
10/09/2009

**Condition category**
Pregnancy and Childbirth

[_] 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

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
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

### Study design
Randomised controlled trial

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Not specified

### Study type(s)
Treatment

### Participant information sheet

### 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 measure
Cord separation time

### Secondary outcome measures
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

### Overall study start date
01/10/2003

### 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

### Age group
Neonate

### Sex
Both

### Target number of participants
670

### 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)

### Sponsor details
An der Wiek 7
Greifswald- Insel Riems
Germany
D-17493

### Sponsor type
Industry

### Website
http://www.riemser.de

### ROR
https://ror.org/01a7r5j51

## Funder(s)

**Funder type**
Industry

**Funder Name**
Riemser AG (Germany)

# 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? |
|---|---|---|---|---|---|
| Results article | results | 01/07/2009 | | Yes | No |