

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	<input type="checkbox"/> Prospectively registered
Registration date 05/10/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 10/09/2009	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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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Contact details

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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