



Trial Description

Title

Health Services Research in care of very-low-birth-weight-infants in NICUs - The impact of human and organizational factors on performance.

Trial Acronym

HSR-NICU

URL of the trial

<http://www.hsr-nicu.de>

Brief Summary in Lay Language

The possibilities in care of premature infants have been fast-paced the last years. In our research project we examine how premature care can further be improved throughout germany. Therefore, we analyze the relationship between the medical care itself, aspects of medical ethics and economic key figures. The following data is collected at more than 60 neonatal intensive care units throughout germany: medical data of premature babies, parents perspective, the way of thinking of physicians and nurses and organizational and cost data of the hospital.

Brief Summary in Scientific Language

Premature birth is the major cause of perinatal acquired disabilities and mortality. The care of very premature infants with a birth weight less than 1,500g is shaped by several factors. Since February 2012 the HSR-NICU project in the field of health services research in care of very low birth weight infants is funded by the Federal Ministry of Education and Research (BMBF). The project aims to analyze the question how and to what extent outcomes of premature births less than 1,500g will be influenced by human and organizational factors.

A pilot study with five german neonatal intensive care units showed that workload, staff attitudes and structural features are influencing the quality of premature care.

In the current multicenter study with over 60 NICUs relationships between working conditions, staff and parent satisfaction, economic and medical factors, goals and organisational procedures are analysed in an interdisciplinary cooperation between medicine, ethics, business administration and sociology.

The methods for data collection are staff and parent questionnaires, medical outcome data as well as general information of participating centres as e.g. processes, costs, structures, capacity, case severity and occupancy.

Results of the interdisciplinary and innovative research project are expected to contribute to the organizational structuring of NICUs and to the design of care structures and processes in the field of Neonatology. Aim is the development and implementation of measures of quality management and improvement in the area of neonatal care.

Organizational Data

- DRKS-ID: **DRKS00004589**
- Date of Registration in DRKS: **2013/05/15**
- Date of Registration in Partner Registry or other Primary Registry: [---]*
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **12-228 , Ethik-Kommission der Medizinischen Fakultät der Universität zu Köln**

Secondary IDs

Health condition or Problem studied

- ICD10: **P07 - Disorders related to short gestation and low birth weight, not elsewhere classified**

Interventions/Observational Groups

- Arm 1: **1) Survey of medical quality indicators of included preterms by three-sided questionnaire about treatment and clinical course parameters after discharge from hospital**
2) parent questionnaires during the hospital stay and 12 month after discharge
3) One-time staff questionnaires for medical and nursing staff
4) survey of general structure information with a questionnaire for the head of neonatology and the responsible controller
5) survey of staff deployment with a shift schedule booklet for nursing staff for a time period of 6 months

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **Single arm study**
- Blinding: [---]*
- Who is blinded: [---]*
- Control: **Uncontrolled/Single arm**
- Purpose: **Other**
- Assignment: **Single (group)**
- Phase: **N/A**



Study Type: **Non-interventional**

Study Type Non-Interventional: **Observational study**

Allocation: **Single arm study**

Blinding: [---]*

Who is blinded: [---]*

Control: **Uncontrolled/Single arm**

Purpose: **Other**

Assignment: **Single (group)**

Phase: **N/A**

- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Survey and analysis of medical quality indicators of included preterms by three-sided questionnaire about treatment and clinical course parameters after discharge from hospital; questionnaire is filled in by the study-responsible physician; only routine data ist collected

Secondary Outcome

One-time staff questionnaires for medical and nursing staff; parent questionnaires during the hospital stay and 12 month after discharge; daily staff fluctuation with a shift schedule booklet for the nursing staff during a time period of 6 month

Countries of recruitment

- **DE Germany**

Locations of Recruitment

- Medical Center **Akk Altonaer Kinderkrankenhaus, Hamburg**
- University Medical Center **Universitätsklinikum Schleswig-Holstein, Lübeck**
- Medical Center **Klinikum Itzehoe, Itzehoe**
- Medical Center **Klinikum links der Weser, Bremen**
- University Medical Center **Universitätsklinikum Greifswald, Greifswald**



- University Medical Center **Charite, Campus Mitte, Berlin**
- University Medical Center **Charite, Campus Virchow, Berlin**
- Medical Center **St. Joseph Krankenhaus, Berlin**
- Medical Center **Vivantes Klinikum Neukölln, Berlin**
- Medical Center **Evangelisches Waldkrankenhaus Spandau, Berlin**
- Medical Center **DRK Kliniken Berlin Westend, Berlin**
- Medical Center **Klinikum Frankfurt (ODER), Frankfurt a.O.**
- Medical Center **Carl-Thiem Klinikum, Cottbus**
- Medical Center **Städtisches Krankenhaus Dresden-Neustadt, Dresden-Neustadt**
- Medical Center **St. Elisabeth und St. Barbara, Halle Saale**
- University Medical Center **Halle Saale, Halle Saale**
- University Medical Center **Magdeburg, Magdeburg**
- Medical Center **Harz-Klinikum, Wernigerode**
- University Medical Center **Düsseldorf, Düsseldorf**
- Medical Center **Helios Klinikum Wuppertal, Wuppertal**
- Medical Center **Marienhospital Bottrop, Bottrop**
- Medical Center **Helios Klinikum, Krefeld**
- University Medical Center **Köln, Köln**
- Medical Center **Klinikum Leverkusen, Leverkusen**
- University Medical Center **Bonn, Bonn**
- Medical Center **St. Marien Hospital, Bonn**
- Medical Center **Asklepios Klinik, Sankt Augustin**
- Medical Center **DRK Kinderklinik, Siegen**
- Medical Center **St. Antonius Hospital, Kleve**
- Medical Center **Kreiskrankenhaus, Gummersbach**
- Medical Center **Bethlehem Hospital Stolberg, Stolberg**
- Medical Center **Marienhospital, Witten**
- Medical Center **Herford, Herford**
- Medical Center **Johannes Wesling Klinikum, Minden**
- Medical Center **St. Vincenz-Krankenhaus, Paderborn**
- Medical Center **Kassel, Kassel**
- University Medical Center **Göttingen, Göttingen**



- Medical Center **Mathias-Spital Rheine, Rheine**
- Medical Center **Evangelisches Krankenhaus, Lippstadt**
- Medical Center **Christophorus-Kliniken Coesfeld, Coesfeld**
- University Medical Center **Frankfurt a.M., Frankfurt a.M.**
- Medical Center **Klinikum, Aschaffenburg**
- Medical Center **Dr. Horst-Schmidt-Kliniken, Wiesbaden**
- University Medical Center **Homburg/Saar, Homburg**
- Medical Center **St. Marienkrankenhaus, Ludwigshafen**
- Medical Center **Worms, Worms**
- Medical Center **Mutterhaus der Borromäerinnen, Trier**
- Medical Center **Diakonie Krankenhaus kreuznacher diakonie, Bad Kreuznach**
- Medical Center **Fulda, Fulda**
- Medical Center **Main-Kinzig-Kliniken, Gelnhausen**
- Medical Center **Stauferklinikum Schwäbisch Gmünd, Mutlangen**
- Medical Center **Esslingen, Esslingen**
- Medical Center **Städtisches Klinikum Karlsruhe, Karlsruhe**
- Medical Center **Hegau-Bodensee-Klinikum, Singen**
- University Medical Center **Freiburg, Freiburg**
- Medical Center **Caritas-Krankenhaus, Bad Mergentheim**
- Medical Center **Memmingen, Memmingen**
- Medical Center **Nürnberg Süd, Nürnberg**
- University Medical Center **Erlangen, Erlangen**
- Medical Center **St. Marien, Amberg**
- Medical Center **Barmherzige Brüder Regensburg, Regensburg**
- Medical Center **Kinderklinik Dritter Order, Passau**
- Medical Center **Donaulsar Klinikum, Deggendorf**
- Medical Center **Sozialstiftung Bamberg, Bamberg**
- University Medical Center **München, München**
- Medical Center **Kinderkrankenhaus St. Marien, Landshut**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2013/05/01**
- Target Sample Size: **1775**
-



Planned/Actual: **Actual**

(Anticipated or Actual) Date of First Enrollment: **2013/05/01**

Target Sample Size: **1775**

Monocenter/Multicenter trial: **Multicenter trial**

■ National/International: **National**

Inclusion Criteria

■ Gender: **Both, male and female**

■ Minimum Age: **2 Weeks**

■ Maximum Age: **no maximum age**

Additional Inclusion Criteria

Newborns <1500g or outborns <1500g if transferral into Nicu takes place within the first 24 hours; birth between 01.05. and 31.10.2013; intensive primary care after birth/treatment in NICU in survey period; one parent speaks german or an interpreter is available;

Exclusion criteria

see inclusion criteria

Addresses

■ Primary Sponsor

**Universität zu Köln
Mr. Prof. Dr. Ludwig Kuntz
Albertus-Magnus Platz
50923 Köln
Germany**

Telephone: [---]*

Fax: [---]*

E-mail: [---]*

URL: [---]*

■ Contact for Scientific Queries

**Universität zu Köln
Mr. Prof. Ludwig Kuntz
Albertus-Magnus Platz
50923 Köln**

Contact for Scientific Queries

Universität zu Köln
Mr. Prof. Ludwig Kuntz
Albertus-Magnus Platz
50923 Köln
Germany

Telephone: **0221-470-5416**

Fax: **0221-470-5418**

E-mail: **kuntz at wiso.uni-koeln.de**

URL: **http://www.mig.uni-koeln.de/**

■ Contact for Public Queries

Universität zu Köln
Mr. Prof. Ludwig Kuntz
Albertus-Magnus Platz
50923 Köln
Germany

Telephone: **0221-470-5416**

Fax: **0221-470-5418**

E-mail: **kuntz at wiso.uni-koeln.de**

URL: **http://www.mig.uni-koeln.de/**

Sources of Monetary or Material Support

- **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

Bundesministerium für Bildung und Forschung Dienstsitz Berlin
Friedrichstraße 130 B
10117 Berlin
Germany

Telephone: [---]*

Fax: [---]*

E-mail: [---]*

URL: **www.bmbf.de**

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2015/12/31**

DRKS-ID: **DRKS00004589**

Date of Registration in DRKS: **2013/05/15**

Date of Registration in Partner Registry or other Primary Registry: [---]*

Trial Publications, Results and other documents

- Paper [---]*

* *This entry means the parameter is not applicable or has not been set.*

*** *This entry means that data is not displayed due to insufficient data privacy clearing.*