Increasing awareness and adherence to infection control in neonatal intensive-care unit (NICU)

Submission date	Recruitment status No longer recruiting	Prospectively registered	
09/03/2016		[_] Protocol	
Registration date	Overall study status	[] Statistical analysis plan	
10/03/2016	Completed	[_] Results	
Last Edited 20/04/2016	Condition category Infections and Infestations	[_] Individual participant data	
		[_] Record updated in last year	

Plain English summary of protocol

Background and study aims

Infection control is a major concern in patient care and particularly so in neonatal intensive care. Infection control (preventing patients from getting infections) is a major concern in patient care, especially for newborn babies (neonates) in neonatal intensive care (a ward to look after ill or premature babies). These patients are extremely vulnerable to infections for a number of reasons, including an undeveloped immune (defense) system, fragile skin, having tubes in place attached to supportive equipment (invasive lines) and even the warmer temperature that is necessary in the unit. Infections gained in hospital (nosocomial infections) are responsible for a significant risk of illness and death, with the most premature infants experiencing the highest rates of all hospitalised patients. It is estimated by the Centres for Disease Control and Prevention that one third of all hospital acquired infections are caused by people not following infection control practices, such as hand washing, properly. There are many strategies designed to help improve hand hygiene in those who work in NICU, including placement of hand hygiene tools (alcohol hand gel, soap and water), training and education, evaluation and feedback of performance, provision of work place reminders and a culture of safety, however strategies aims directly at patient visitors are limited. The aim of this study is to find out if a computerised audiovisual infection control initiative (CAVICI) system (a computerised system designed to encourage visitors to better adhere to infection control practices) is able to help improve hand hygiene in patient visitors and lower nosocomial infection rates in NICUs.

Who can participate?

Any visitor to the NICU aged 16 years and over.

What does the study involve?

A computerised multilingual audio-visual display monitor (CAVICI) instructing on correct hand washing and infection control standards (ICS) is installed at entrance to NICUs in the study hospitals. Participating parents and visitors are asked some questions to assess their knowledge of infection control and are then asked whether they would mind having their hands sponged to assess the organisms on their hands. Parents are also watched while they are on the ward discretely in order to assess their hand washing technique and adherence to correct infection control.

What are the possible benefits and risks of participating?

Participants will benefit from learning correct infection control methods which will lower the risk of them infecting their baby. There are no risks involved with taking part in the study.

Where is the study run from? Bolton NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for? January 2014 to December 2016

Who is funding the study? Cow and Gate and Say Communications (UK)

Who is the main contact? Miss Jean Walker

Contact information

Type(s) Public

Contact name Miss Claire Fish

Contact details Bolton NHS Foundation Trust, Minerva Road, Farnworth Bolton United Kingdom BL4 0JR

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers 19174

Study information

Scientific Title

Prospective interventional study to increase infection control compliance and decrease nosocomial infection rates across Greater Manchester tertiary NICUs by the installation of a computerised audiovisual infection control initiative (CAVICI) system.

Study objectives

The aim of this study is to:

1. Increase knowledge and adherence to infection control by parents and patient visitors to the tertiary NICUs across the Greater Manchester Region, by the installation of a multilingual computerised audiovisual infection control initiative (CAVICI) system

2. Improve hand hygiene by reducing bacterial hand contamination

3. Determine whether the installation of a CAVICI system can decrease nosocomial infection rates in neonates admitted to NICUs across Greater Manchester

Ethics approval required

Old ethics approval format

Ethics approval(s)

North West - Greater Manchester East Research Ethics Committee, 19/03/2015, ref: 15/NW/0230

Study design

Non-randomised study

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Topic: Children; Subtopic: Children (all Diagnoses); Disease: All Diseases

Interventions

A total of 64 covert patient visitor observations for adherence to 5 infection control standards (ICS) to be studied across the hospital sites, namely:

- 1. Removal of jackets
- 2. Rolling up of sleeves
- 3. Removal of all hand & wrist jewellery/watches

4. Thorough hand washing, defined as 30 second hand wash +/- emulation of correct method as on video screen. Namely 6 steps, rub palms together to create lather, rub backs of hands with palms with fingers interlaced, wash between fingers, group fingers together and rub tips in

lather on palm of opposite hand, rotational rubbing of left thumb clasped in right palm and vice versa and rub backs of fingers against opposite palm prior to rinsing. 5. Thorough hand gelling (30 seconds)

A computerised multilingual audio-visual display monitor (CAVICI) instructing on correct hand washing and the 5 infection control standards (ICS) will be installed at entrance to NICUs in the study hospitals. Covert observation of patient visitor on entrance to NICU and observation until patient visitor reaches patient cot-side and +/- handles patient. Observation of adherence to 5 ICS on entrance to NICU to the cot-side. Bacteriological surveillance involving sterile sponges rubbed over participants hands which then are cultured for organisms present.

Participants are followed up one and six months after the CAVICI is installed.

Intervention Type

Other

Primary outcome measure

1. Adherence rates by patient visitors to NICU, of the 5 infection control standards pre-, 1 month and 6 months post-intervention

2. Awareness rates amongst visitors of the 5 infection control standards, pre- and 6 months postintervention

3. Hand bacteriological contamination rates of patient visitors to NICU, pre- and 6 months postintervention

4. Nosocomial infection rates on NICUs pre- and post- intervention

Secondary outcome measures

No secondary outcome measures

Overall study start date

05/01/2014

Completion date

01/02/2017

Eligibility

Key inclusion criteria Any visitor to the NICU over age of 16.

Participant type(s) Patient

Age group Adult

Sex Both

Target number of participants Planned Sample Size: 128; UK Sample Size: 128

Key exclusion criteria Under 16 years of age.

Date of first enrolment 06/03/2016

Date of final enrolment 01/12/2016

Locations

Countries of recruitment England

United Kingdom

Study participating centre Royal Bolton Hospital

Minerva Road Farnworth Bolton United Kingdom BL4 0JR

Study participating centre Royal Oldham Hospital Rochdale Road Oldham Manchester United Kingdom OL1 2JH

Sponsor information

Organisation Bolton NHS Foundation Trust

Sponsor details Minerva Road Farnworth Bolton England United Kingdom BL4 0JR

Sponsor type Hospital/treatment centre

ROR https://ror.org/03y9bvk93

Funder(s)

Funder type Industry

Funder Name Cow and Gate and Say Communications

Results and Publications

Publication and dissemination plan

Planned publication of study results in a peer reviewed journal.

Intention to publish date 01/06/2017

Individual participant data (IPD) sharing plan

IPD sharing plan summary Available on request

Study outputs					
Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<u>HRA research summary</u>			28/06/2023	No	No