ISRCTN58085619 https://doi.org/10.1186/ISRCTN58085619

Improving the care of ventilated preterm babies by weighing them within the incubator

Submission date 12/03/2015	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 18/03/2015	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 04/07/2017	**Condition category** Neonatal Diseases	[_] Individual participant data

Plain English summary of protocol

Background and study aims
Currently when looking after babies in intensive care, doctors do not have an ability to weigh them accurately if they are ventilated. This means that sick babies have to be disconnected from the artificial breathing machine (ventilator) in order to weigh them. They are then weighed on standalone electronic scales, without the ventilator attached. Since most sick babies do not tolerate this procedure, they are not weighed and this means that medicines, fluids and electrolytes are calculated by estimation (guessing) their weight, which potentially can lead to over or under dosing.
This study aims to determine whether we could safely and accurately weigh ventilated babies within the incubator on integral incubator scales, whilst still connected to the ventilator, by comparing their weight with and without a ventilator tube compensator device against their true (electronic standalone scale) weight.

Who can participate?
Any ventilated stable baby

What does the study involve?
We weighed ventilated babies within the incubator on integral incubator scales, whilst still connected to the ventilator, and compared their weight with and without a ventilator tube compensator device against their true (electronic standalone scale) weight, whilst disconnected from the ventilator.

What are the possible benefits and risks of participating?
No direct benefit for infant and no anticipated risks, since only carried out in stable ventilated babies.

Where is the study run from?
Salford Royal Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
February 2009 to August 2011

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Ula El-Kafrawy

Contact information

Type(s)
Scientific

Contact name
Dr Ula El-Kafrawy

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Optimising the care of ventilated infants by weighing accurately on incubator scales

Study objectives
Assessing the accuracy of integral incubator scales in weighing ventilated infants

Ethics approval required
Old ethics approval format

Ethics approval(s)
Cambridgeshire 2 Ethics Committee, 09/04/2008, REC ref: 08/H0308/35

Study design
Diagnostic accuracy study

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Assessing the accuracy of integral incubator scales in weighing ventilated infants

Interventions
Comparison of weights of ventilated infants when weighed on incubator scales against true weight

Intervention Type

Primary outcome(s)
The weight of the ventilated baby was compared by 2 different methods, one by weighing on incubator scales whilst ventilated and one by weighing on freestanding electronic scales whilst not ventilated, the weights were done at baseline within a few minutes of each other. They were then compared by the statistical method of Bland and Altman.

Key secondary outcome(s))
Inaccuracy correctable by use of a ventilator tube compensator device

Completion date
01/08/2011

Eligibility

Key inclusion criteria
Any ventilated baby

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Neonate

Sex
All

Key exclusion criteria
No exclusion criteria.

Date of first enrolment
01/06/2009

Date of final enrolment
01/02/2011

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Royal Salford Hospital
Salford
Manchester
United Kingdom
M6 8HD

Sponsor information

Organisation
Royal Salford NHS Trust

ROR
https://ror.org/019j78370

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Royal Salford NHS Trust

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2016		Yes	No