

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

<b>Submission date</b> 12/03/2015	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 18/03/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 04/07/2017	<b>Condition category</b> Neonatal Diseases	<input type="checkbox"/> 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

**Contact details**  
Royal Bolton Hospital  
Bolton  
Manchester  
Manchester  
United Kingdom  
BL4 0JR

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
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

**Secondary study design****Study setting(s)**

Hospital

**Study type(s)**

Diagnostic

**Participant information sheet****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 measure**

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.

**Secondary outcome measures**

Inaccuracy correctable by use of a ventilator tube compensator device

**Overall study start date**

01/02/2009

**Completion date**

01/08/2011

**Eligibility****Key inclusion criteria**

Any ventilated baby

**Participant type(s)**

Patient

**Age group**

Neonate

**Sex**

Both

**Target number of participants**

30

**Key exclusion criteria**

No exclusion criteria.

**Date of first enrolment**

01/06/2009

**Date of final enrolment**

01/02/2011

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Royal Salford Hospital**

Salford

Manchester

United Kingdom

M6 8HD

## **Sponsor information**

**Organisation**

Royal Salford NHS Trust

**Sponsor details**

Stott Lane

Salford

England

United Kingdom

M6 8HD

**Sponsor type**

Hospital/treatment centre

**ROR**

<https://ror.org/019j78370>

# Funder(s)

## Funder type

Hospital/treatment centre

## Funder Name

Royal Salford NHS Trust

# Results and Publications

## Publication and dissemination plan

To publish a medical paper for a paediatric/neonatal journal and currently submitting for publication to the Archives of disease in Children, Fetal & Neonatal edition.

## Intention to publish date

31/12/2015

## 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?
<a href="#">Results article</a>	results	01/12/2016		Yes	No