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Is additional information about Neonatal body water (Bioelectrical Impedance Analysis) useful to clinicians who are making decisions about fluid management in the NICU? A feasibility randomised controlled trial

Submission date 14/11/2024	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 15/11/2024	**Overall study status** Ongoing	
Last Edited 15/11/2024	**Condition category** Neonatal Diseases	

Plain English summary of protocol

Background and study aims

This study aims to find out if using Bioelectrical Impedance Analysis (BIA) helps doctors decide how much fluid to give to premature or ill newborns through a drip. BIA uses a non-invasive device to measure the amount of fluid in a baby's body. Proper fluid management can affect many aspects of a baby's care, including how long they need breathing support, when they can start feeding, and how long they stay in the hospital.

Who can participate?

All babies who are likely to need fluids through a drip during their first week of life can participate. The study includes babies who are less than 30 weeks gestation, babies who are 30-36 weeks, and term babies who have received intensive care in the first 24 hours of life. Parents and staff in the Neonatal Intensive Care Unit (NICU) can also participate in interviews and observations.

What does the study involve?

Babies will be randomly assigned to either receive daily BIA measurements (BioScans) or not. If they receive BioScans, these will be done daily for 28 days and then weekly until they leave the hospital. The information from these scans will help doctors make decisions about fluid management. Doctors will record how useful they find this information each day. Researchers will also observe ward rounds and interview staff and parents about their opinions on the device.

What are the possible benefits and risks of participating?

There will not be any direct benefits to the baby from participating in the study. However, the findings may help improve care for future babies. The main risk is that the electrodes used for BIA might cause some minor skin irritation, but this will not be long-lasting.

Where is the study run from?
Liverpool Women's Hospital (UK)

When is the study starting and how long is it expected to run for?
October 2022 to November 2026

Who is funding the study?
Liverpool Women's NHS Foundation Trust (UK)

Who is the main contact?
Colin.Morgan@lwh.nhs.uk
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Contact information

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Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
342736

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
LWH1358

Study information

Scientific Title
A feasibility Randomised controlled trial to compare Additional Information on Neonatal BOdy Water distribution (RAINBoW) with standard care

Acronym
RAINBoW

Study objectives
This is a mixed methods study which aims to determine if Bioelectrical Impedance Analysis (BIA) is clinically useful when used within fluid management decisions in preterm and sick term infants and to determine if it improves clinical outcomes.

Null-Hypothesis
The provision of BIA information will have no effect upon the effectiveness of fluid management decisions in the preterm and term population in the NICU, indicated by a serum sodium outside the range of (132 mmols/L-143mmols/L) and extreme fluctuations (<125mmols/L >150 mmols/L).

Observational studies will be used in the clinical setting to watch the use of the device, and interviews will explore the views of staff and parents regarding the clinical utility of the Bioscan (Bioelectrical Impedance Device).

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 30/10/2024, Yorkshire & The Humber - Bradford Leeds Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle Upon Tyne, NE2 4NQ, United Kingdom; +44 2071048083; bradfordleeds.rec@hra.nhs.uk), ref: 24/YH/0230

Study design
Single centre feasibility randomised controlled trial with nested qualitative study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Efficacy

Participant information sheet
See outputs table

Health condition(s) or problem(s) studied

The use of bioelectrical impedance in fluid management decisions within the neonatal population.

Interventions

All babies will be randomised to either Bioscan or Standard Care (no Bioscan). This will be carried out on admission by an Advanced Practitioner / Team Leader or Consultant. The randomisation software "Sealed Envelope" will be used to randomise.

All babies who are randomised to the intervention arm of the trial, will have daily (or more frequent if requested) bioelectrical impedance measurements (Bioscan) taken by the bedside nurse prior to the morning ward round. This will happen daily (or more frequently) for the first 28 days and weekly thereafter. This Bioscan data will be made available to the clinical team at the morning ward round to provide additional information to guide their decision-making about fluid and electrolyte management.
The Bioscan will be used to generate a morning summary dataset for each baby in the intervention arm of the trial.
• This will be generated by the bedside nurse and made available via the machine or via the electronic patient record to the nurse and doctor/ANNP responsible for the intervention group in advance of the 10.30 ward round where possible.
• The control group will not have a Bioscan reading taken and therefore this information will not be available to the clinical team.
Staff will register how clinically useful they have found the information following the fluid management discussion via a feedback sheet.

The control group will receive standard care and not have Bioscan measurements taken. Data collection from the EPR will be the same as for both patient groups. This study ends at discharge and there will not be any follow up.

30 semi-structured ward round observations will take place to observe the machine in clinical practice.
30 Semi-structured interviews will take place with clinicians and they will be asked about the perceived clinical utility of the machine.
30 Semi-structured interviews will take place with parents of babies who are on the trial to ask about their opinion of the device.
The interviews and observations will be carried out by the principal investigator.

Intervention Type

Other

Primary outcome measure

Serum sodium levels measured using ... at daily intervals for up to 14 days

Secondary outcome measures

1. Feasibility and accuracy of patient, staff, and parent recruitment, ability to collect data, and parental and staff consent rates are measured using recruitment and data sets at ongoing intervals
2. Body water distribution (extracellular fluid, intracellular fluid, interstitial fluid, intravascular fluid) is measured using Bioscan daily for 28 days and once weekly until discharge
3. Cumulative daily nutritional intake and fluid balance (carbohydrate/lipid/protein in g/kg and calories in kcal/kg) are measured using nutritional charts on electronic patient record (EPR) daily for 28 days

4. Estimated mean daily blood glucose levels, including insulin use, are measured using routine blood glucose tests on EPR for the first 14 days of life
5. Growth (weekly change in weight, length, and head circumference) is measured using EPR daily for 28 days and then at discharge
6. Mean serum electrolyte levels are measured using routine blood monitoring tests on EPR for the first 14 days of life
7. Weekly change in total body mineral content is measured using routine blood tests on EPR at weekly intervals
8. Mean serum mineral levels and other biochemical measures of bone biochemistry, including parathyroid hormone levels, are measured using routine blood monitoring tests on EPR as clinical condition dictates
9. Duration of respiratory support (both invasive and non-invasive) is measured using EPR daily for 28 days and at discharge
10. Frequency of circulatory support, including inotropic support, hydrocortisone, and fluid boluses, is measured using EPR daily for 28 days and at discharge
11. Duration of IV fluid therapy (days) is measured using EPR daily for 28 days and at discharge
12. Adverse events associated with IV fluid therapy (e.g., extravasation, limb ischemia) are measured using EPR daily for 28 days and at discharge
13. Infant length of stay in the neonatal unit is measured using EPR at discharge
14. Presence of preterm morbidities in the <29-week gestation cohort (e.g., necrotizing enterocolitis, sepsis, diagnosis of AKI, patent ductus arteriosus, bronchopulmonary dysplasia) is measured using EPR daily for 28 days and at discharge

Embedded Qualitative Study:
This embedded qualitative work will explore clinician practice 'in the real world' as well as parental and clinician-reported perceptions of the device regarding the five aspects of the clinical utility framework outlined below (Smart, 2006), as well as aspects of the trial design in this context. These aspects will form the basis of the interview questions and observations.
1. Appropriateness (relevance)
2. Accessibility (Resource implications)
3. Adherence
4. Practicality (Functionality/Suitability/Training)
5. Acceptance (To Clinician/Family)

Overall study start date
01/10/2022

Completion date
30/06/2027

Eligibility

Key inclusion criteria
Feasibility RCT:
All neonates admitted to the Liverpool Women's Hospital NICU within 24 hours of birth who require intravenous fluid management for the first week of life

Embedded Qualitative Study:
4. All clinical staff working in the NICU
5. Parents of babies who are NICU patients enrolled in the study

Participant type(s)
Patient, Health professional, Service user

Age group
Mixed

Lower age limit
0 Days

Upper age limit
70 Years

Sex
Both

Target number of participants
170 Infants (85 in each arm), up to 30 Staff Members, up to 30 Parents/Family Members

Key exclusion criteria
Feasibility RCT and Embedded Qualitative Study:
1. They a have life limiting condition and the Consultant prognosis is that they will not survive the first week of life
2. They are being nursed in isolation for maternal/infant COVID or another infection, that prevents the device from being used (because of contamination risk)
3. Parents who are unable to understand study information and are deemed unable to make an informed a decision to opt out

Date of first enrolment
25/11/2024

Date of final enrolment
30/11/2026

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
The Liverpool Women's Hospital
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Sponsor information

Organisation
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Sponsor type
Hospital/treatment centre

Website
http://www.liverpoolwomens.nhs.uk/Support_Us/Liverpool_Womens_Charity.aspx

ROR
https://ror.org/00eysw063

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Liverpool Women's NHS Foundation Trust

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The feasibility RCT will form part of the PhD thesis of the principal investigator. The results will also be written up and presented at a future Neonatal Society and advanced practice conferences such as ESPNIC / COIN / Nutrition and Growth. It will also be written up for publication in the scientific journals. Social Media (Twitter, LinkedIn) will be used judiciously to disseminate findings widely and rapidly and a lay summary will be produced. A Study Twitter account @RAINBoW-NICU will be set up to facilitate dissemination more widely. The lay summary of the results will be co-produced with PPI representatives, and this will be presented at parent representative groups (BLIS) and shared on social media.
The embedded qualitative study findings will be presented as the PhD thesis for the PI. The study results will be presented within peer review journals and professional conference proceedings. The PI will work with the advisory PPIE panel to write a short lay summary for each part of the project and a final Plain English summary of the work undertaken and the outcome. The aim of this summary will be to make the information accessible to as many people as possible.

Intention to publish date
30/06/2028

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date