

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	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 15/11/2024	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 15/11/2024	Condition category Neonatal Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

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?
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Contact information

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

342736

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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

Study type(s)

Efficacy

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(s)

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

Key secondary outcome(s)

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)

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

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

0 days

Upper age limit

70 years

Sex

All

Key exclusion criteria

Feasibility RCT and Embedded Qualitative Study:

1. They have a 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 decision to opt out

Date of first enrolment

25/11/2024

Date of final enrolment

30/11/2026

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

The Liverpool Women's Hospital

CROWN STREET

Liverpool

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L8 7SS

Sponsor information**Organisation**

Liverpool Women's Hospital

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

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