

Support at home for infants with feeding tubes (SHIFT)

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| Submission date 08/02/2012 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 09/03/2012 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results |
| Last Edited 19/05/2017 | 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

About 1 in every 10 babies in the UK is born early and many need care on a special care baby unit (SCBU) for weeks. In the few weeks before they go home most just need relatively straightforward help receiving some milk through a tube that goes into the stomach (nasogastric tube). In Newcastle we have helped some parents take their baby home from hospital early with this feeding tube still in place, supported with nurse visits. This seems safe and may have lots of health benefits (decreased infections, better bonding), may save the NHS money and free-up space in SCBUs. But, we do not know if it makes a difference to breast-feeding or growth, and some parents may be more anxious caring for their baby at home sooner. Because early discharge with home support affects the baby, the parents and the NHS, we need to find out more, and we have designed this study to try to do this. We aim to explore infant, parental and NHS perspectives on the two approaches, looking at parental anxiety measures, infant growth, feeding, infection rates, and NHS costs and benefits to services from free neonatal intensive care capacity.

Who can participate?

Babies born early and cared for by Newcastle neonatal service may take part in this study. They will be offered the chance to take part when they are otherwise medically well, and their only reason for remaining in hospital is that they are not quite ready to take all their feeds by mouth. Babies can only take part if their parents agree to this.

What does the study involve?

100 preterm babies will be randomly allocated to two groups. In one group they are cared for in the normal way, which is to stay in hospital until they no longer need a feeding tube. The other half will be supported by staff to take their baby home with a feeding tube in place and parents and community support staff (nurses) will gradually move their baby to oral feeding at home rather than in hospital.

What are the possible benefits and risks of participating?

We are not sure what the exact benefits and risks for each group are, which is why we need to do the study. Areas that we think may be importantly different are whether parents prefer one or other practice and how this might affect their anxiety levels. We also might see differences in

the health of the baby including differences in growth and weight gain, infections and how long breast-feeding is successfully maintained. We do not believe there are any serious risks from taking a baby home with a feeding tube in, and we have supported parents to do this outside of a study in the past. Because care at home is likely to be less expensive than care in a hospital we will also work out the health care costs for the two strategies. This would be an important consideration if the innovation was to be more widely adopted.

Where is the study run from?

The Newcastle neonatal service. We are a large nursery with experience of caring for babies and their families in hospital and after discharge. We have talked to many parents about this idea, and parents have helped us design this study.

When is the study starting and how long is it expected to run for?

The study started in summer 2012, and it will take 2 years to complete the study.

Who is funding the study?

The study is funded by BLISS the special care baby charity through a special fund called the innovation fund. This looks to support new and innovative ways to support babies and their families.

Who is the main contact?

Dr Nicholas Embleton

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Contact information

Type(s)

Scientific

Contact name

Dr Nicholas Embleton

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

V1

Study information

Scientific Title

Support at home for infants with feeding tubes (SHIFT)

Acronym

SHIFT

Study objectives

To determine the key benefits for infant and family health, and the NHS, of early discharge home with supported tube feeding in preterm infants.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial: early discharge with home tube feeding vs standard care

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Quality of life

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

Preterm infants

Interventions

Discharge home with a feeding tube versus standard care, which is to remain in hospital until the feeding tube is no longer needed.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Infant outcome measures:

1. Growth (weight, head circumference and length) weekly until discharged from community care (or discharged home for standard care group) and then monthly to 3 months for all
2. Feeding method (exclusive breast, formula or mixed feeding)
3. Infection episodes (defined as treatment by a medical practitioner for suspected infection)
4. Re-admission rates (defined as number of episodes requiring re-hospitalisation as an in-patient)

Parental measures

Anxiety state/trait questionnaire administered twice once at the point of discharge home, and again at 3 months of corrected age. This will be measured using the Spielberger State-Trait Anxiety Inventory which is well validated and currently used in some of our other studies with parents of newborn babies.

Economic data and analysis:

Costings will be calculated for community nursing visits required, any additional input received from the primary care team, consumable costs (feeding tubes, syringes etc) and days of hospital care received.

Secondary outcome measures

No secondary outcome measures

Overall study start date

01/05/2012

Completion date

01/05/2014

Eligibility

Key inclusion criteria

1. Preterm infants <37 weeks gestation
2. Unable to fully orally feed
3. Able to take at least one reasonable volume/duration oral feed
4. Expected to fully orally feed within the next 2 - 4 weeks
5. No medical requirement for continuing hospitalisation
6. Signed parental consent

Participant type(s)

Patient

Age group

Neonate

Sex

Both

Target number of participants

100

Key exclusion criteria

Infants with underlying problems such that tube feeding is not likely to be a temporary need (for example, brain injured infants or those with congenital abnormalities)

Date of first enrolment

01/05/2012

Date of final enrolment

01/05/2014

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

Royal Victoria Infirmary

Newcastle

United Kingdom

NE1 4LP

Sponsor information**Organisation**

Newcastle upon Tyne Hospitals NHS Foundation Trust (UK)

Sponsor details

Royal Victoria Infirmary

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Sponsor type

Hospital/treatment centre

Website

<http://www.newcastle-hospitals.org.uk/news/best-of-nuth.aspx>

ROR

<https://ror.org/05p40t847>

Funder(s)

Funder type

Charity

Funder Name

Bliss (UK)

Alternative Name(s)

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration