

# Speed of Increasing milk Feeds Trial

<b>Submission date</b> 05/03/2013	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 14/03/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 23/08/2021	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Survival of preterm infants has increased greatly over the years, so a major aim now is to improve the long-term outlook for these infants and to avoid serious complications. The way infants are fed in early life affects short- and long-term health and survival. Because the bowels of preterm infants have not matured, they cannot digest large volumes of milk feeds straight away. Until the gut matures, nutrition is provided by intravenous drip while the amount of milk given is gradually increased over time. Increasing the amount of milk rapidly may increase the risk of gut complications. Increasing the amount of milk given more slowly means that intravenous nutrition is needed for longer; there is an associated risk of infection proportional to the time the intravenous line is present in the bloodstream of these infants. Despite the importance of milk feeding preterm infants, there have been few studies to inform how best to balance these risks, and what the best way to increase feeds in these infants is - this study sets out to address this missing information. The study will compare two different rates of increase of milk feeds, one faster and one slower, both within rates currently used in UK neonatal units. The study aims to find out if either rate gives better outcomes for the infants. Investigators will measure a variety of outcomes, such as survival without disability, infection, bowel problems, growth and long-term physical and mental development, as well as the impact on families and the NHS, including costs. The study will be led by an established team of researchers who have run similar studies before, and will use an established network of neonatal units that have taken part in previous studies.

### Who can participate?

The study will recruit 2800 very preterm (<32 weeks) or VLBW (<1,500 g) infants from 58 neonatal units within the UK and Ireland over 3 years.

### What does the study involve?

With informed consent from parents, infants will be randomly allocated to receive either faster (30 ml/kg/day) or slower (18 ml/kg/day) increases in milk feed volumes. As well as assessing the effect of a faster feeding increment on the risk of severe or moderate disability, the study will also compare the rate of serious infection and necrotising enterocolitis [portions of the bowel undergo necrosis (tissue death)], the time taken to reach full milk feeds, the duration of nutrition is provided by intravenous drip, growth, and the length of hospital stay between the

two groups. Infants will be followed up at 2 years of age via a questionnaire which will be posted to the parents. Finally, an economic evaluation will be undertaken to determine whether faster feeding advancement is a cost-effective treatment.

What are the possible benefits and risks of participating?

There will be no immediate direct benefit to those taking part in the study; however, there should be benefits to future very preterm or VLBW babies as the results of the study are likely to influence NHS neonatal feeding policy and practice. As both the study rates of increase of milk feeds (faster and slower) are within rates currently used in UK neonatal units, there is no difference in risk between feeding regimens administered as part of the study and those administered as part of standard clinical care.

Where is the study run from?

SIFT is run from the National Perinatal Epidemiology Unit Clinical Trials Unit at the University of Oxford (UK).

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

Recruitment started in summer 2013 and finished in summer 2015. Follow-up will start 2 years after the first infants are recruited (summer 2015) and continue until 2 years after the last infants are recruited (summer 2015).

Who is funding the study?

NIHR Health Technology Assessment Programme - HTA (UK)

Who is the main contact?

Chief Investigator, Jon Dorling: [Jon.Dorling@iwk.nshealth.ca](mailto:Jon.Dorling@iwk.nshealth.ca)

Trial Coordinator: [sift@npeu.ox.ac.uk](mailto:sift@npeu.ox.ac.uk)

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

[ClinicalTrials.gov \(NCT\)](https://clinicaltrials.gov/ct2/show/study/NCT01711111)

NCT01727609

**Protocol serial number**

HTA 11/01/25

## Study information

**Scientific Title**

A multi-centre randomised controlled trial of two speeds of daily increment of milk feeding in very preterm or very low birth weight infants

**Acronym**

SIFT

**Study objectives**

It is hypothesised that the proportion of very preterm (<32 weeks) or very low birth weight [VLBW] (<1,500 g) infants surviving without moderate or severe disability at 24 months post menstrual age will be greater in the faster (30 ml/kg/day) versus slower (18 ml/kg/day) increasing milk feed regimen.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

NRES Committee East Midlands - Nottingham 2, 31/01/2013, ref: 13/EM/0030

**Study design**

Phase III multi-centre open-label randomised controlled trial

**Primary study design**

Interventional

**Study type(s)**

Prevention

**Health condition(s) or problem(s) studied**

Neonatal feeding, preterm infants, very low birth weight infants, necrotising enterocolitis, late-onset invasive infection

**Interventions**

The study will recruit 2800 very preterm or VLBW from 58 neonatal units within the UK and Ireland over 3 years.

Infants will be randomly allocated to receive either faster (30 ml/kg/day) or slower (18 ml/kg/day) increases in milk feed volumes. Until discharge they will be monitored for late-onset invasive infection, necrotising enterocolitis, time taken to reach full milk feeds, growth, duration of parenteral feeding, length of hospital stay, and length of time in intensive care.

They will be assessed for moderate or severe disability at 24 months post menstrual age.

## Intervention Type

Other

## Phase

Phase III

## Primary outcome(s)

Moderate or severe disability at 24 months post menstrual age

## Key secondary outcome(s)

Current secondary outcome measures as of 28/04/2016:

1. Survival to discharge home
2. Incidence of microbiologically-confirmed or clinically suspected late-onset infection from trial entry until hospital discharge
3. NEC (Bell stage 2 or 3) from trial entry
4. Time taken to reach full milk feeds (tolerating 150 ml/kg/day for 3 consecutive days)
5. Growth (weight and head circumference) when discharged home
6. Duration of parenteral feeding
7. Length of time in intensive care
8. Length of hospital stay
9. Diagnosis of cerebral palsy by a doctor or other health professional (parent reported)

Previous secondary outcome measures:

1. Incidence of microbiologically-confirmed or clinically suspected late-onset invasive infection from trial entry until hospital discharge
2. Incidence of necrotising enterocolitis (NEC) [Bell stage 2 or 3]
3. Time taken to reach full milk feeds (tolerating 150 ml/kg/day for 3 consecutive days)
4. Growth (weight and head circumference) at discharge
5. Duration of parenteral feeding before discharge
6. Length of time in intensive care
7. Length of hospital stay

## Completion date

10/05/2018

## Eligibility

### Key inclusion criteria

1. Gestational age at birth <32 weeks, or birth weight <1,500 g
2. The infant is receiving  $\leq 30$  ml/kg/day of milk at randomisation
3. Written informed parental consent is obtained

To ensure the widest applicability to preterm infants across the UK, those exclusively breast milk fed, formula milk fed, or receiving mixed feeds will be included.

### Participant type(s)

Patient

### Healthy volunteers allowed

No

**Age group**

Neonate

**Sex**

All

**Total final enrolment**

2804

**Key exclusion criteria**

1. Infants with a severe congenital anomaly
2. Infants who, in the opinion of the treating clinician, have no realistic chance of survival
3. Infants who are unlikely to be traceable for follow-up at 24 months of age (for example, infants of non-UK residents)

**Date of first enrolment**

01/06/2013

**Date of final enrolment**

31/05/2015

**Locations****Countries of recruitment**

United Kingdom

England

Ireland

**Study participating centre**

**NPEU Clinical Trials Unit**

Oxford

United Kingdom

OX3 7LF

**Study participating centre**

**58 other sites**

United Kingdom

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**Sponsor information**

## Organisation

University of Oxford (UK)

## ROR

<https://ror.org/052gg0110>

## Funder(s)

### Funder type

Government

### Funder Name

Health Technology Assessment Programme

### Alternative Name(s)

NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

### Funding Body Type

Government organisation

### Funding Body Subtype

National government

### Location

United Kingdom

## Results and Publications

### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request.

### IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	10/10/2019	10/10/2019	Yes	No
<a href="#">Results article</a>	results	01/04/2020	29/04/2020	Yes	No
<a href="#">Results article</a>	Study Within A Trial (SWAT)	21/08/2021	23/08/2021	Yes	No
<a href="#">Protocol article</a>	protocol	28/01/2017		Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No

<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes