

# Enteral LactoFerrin In Neonates

<b>Submission date</b> 05/06/2013	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 13/06/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 14/01/2019	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

About 20% of very preterm infants (born before 32 weeks) acquire a serious infection. These infants are more likely to develop other problems including severe lung and bowel conditions, and have a higher risk of dying or being disabled. Better methods of preventing infection in very preterm infants are needed. This study will test whether giving them supplemental lactoferrin (a natural antibiotic protein from cow's milk) reduces the number of serious infections.

### Who can participate?

We will invite participation from 2,200 very preterm infants (<32 weeks) cared for in neonatal units across the UK.

### What does the study involve?

Parents will be offered information about the study and will have 72 hours to consider and give their informed consent. Infants will be randomly allocated to receive either lactoferrin or placebo (dummy) mixed with their milk. Neither doctors nor parents will be aware of what supplement the infants will receive. Treatment will continue until the infants are no longer at high risk of acquiring serious infections. As well as comparing serious infection rates between the two groups, we will also assess what effects this supplement has on the risk of other serious diseases and death, on the need for infants to receive multiple or prolonged courses of antibiotics and on the length of hospital stay.

### 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 babies as the results of the study are likely to influence the NHS policy and practice.

### Where is the study run from?

The study 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 will start with six centres in the North of England, as part of a planned 9-month pilot, in September 2013. Following this, the study will be opened in further centres in England, Scotland and Northern Ireland and continue to recruit for a further three years.

Who is funding the study?

The National Institute for Health Research's Health Technology Assessment Programme (NIHR HTA)

has provided the funding for the study.

Who is the main contact?

Chief Investigator, Professor William McGuire: William.McGuire@hyms.ac.uk

Trial Co-ordinator, James Griffiths: james.griffiths@npeu.ox.ac.uk

### **Study website**

<http://www.npeu.ox.ac.uk/elfin>

## **Contact information**

### **Type(s)**

Scientific

### **Contact name**

Prof William McGuire

### **Contact details**

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## **Additional identifiers**

### **EudraCT/CTIS number**

2012-004260-22

### **IRAS number**

### **ClinicalTrials.gov number**

### **Secondary identifying numbers**

ELFIN01

## **Study information**

### **Scientific Title**

A multi-centre randomised placebo-controlled trial of prophylactic enteral lactoferrin supplementation to prevent late-onset invasive infection in very preterm infants

### **Acronym**

ELFIN

**Study objectives**

It is hypothesised that the proportion of very preterm (<32 weeks postmenstrual age) infants with at least one episode of late-onset invasive infection by the time of discharge from hospital will be lower in the lactoferrin group versus the placebo group

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

National Research Ethics Service (NRES) Committee East Midlands - Nottingham 2, Ref: 13/EM/0118, Date: 02/04/2013

**Study design**

Phase III multi-centre placebo-controlled randomised controlled trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Prevention

**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, necrotising enterocolitis, late-onset invasive infection, lactoferrin

**Interventions**

Infants will be randomly allocated to receive either lactoferrin (150 mg/kg/day to a maximum of 300 mg) or placebo. Until discharge they will be monitored for late-onset invasive infection, necrotising enterocolitis, bronchopulmonary dysplasia, retinopathy of prematurity, length of hospital stay and length of time in intensive care.

**Intervention Type**

Drug

**Phase**

Phase III

**Drug/device/biological/vaccine name(s)**

Lactoferrin

**Primary outcome measure**

The incidence of microbiologically-confirmed or clinically suspected late-onset infection from trial entry until hospital discharge. Clinicians will record whether or not infants have been treated for late-onset infection on the data collection form, however we are not recording specific test results.

### **Secondary outcome measures**

1. All-cause mortality prior to hospital discharge
2. Necrotising enterocolitis (NEC): Bell's stage II or III
3. Severe retinopathy of prematurity (ROP) treated medically or surgically
4. Bronchopulmonary dysplasia (BPD): infant is still receiving mechanical ventilator support or supplemental oxygen at 36 weeks' postmenstrual age
5. A composite of invasive infection, major morbidity (NEC, ROP, or BPD as defined above) and mortality
6. Total number of days of administration of antibiotics per infant from 72 hours until death or discharge from hospital
7. Total number of days of administration of antifungal agents per infant
8. Total length of stay until discharge home
9. Length of stay in (i) intensive care, (ii) high dependency care, (iii) special care

### **Overall study start date**

01/03/2013

### **Completion date**

31/05/2018

## **Eligibility**

### **Key inclusion criteria**

Infants will be eligible to participate if:

1. Gestational age at birth is less than 32 weeks
2. Less than 72 hours old
3. Written informed parental consent is obtained

If infants are receiving antibiotic treatment for suspected or confirmed Infection, they are still eligible for recruitment.

### **Participant type(s)**

Patient

### **Age group**

Neonate

### **Sex**

Both

### **Target number of participants**

2200 (including pilot phase)

### **Key exclusion criteria**

1. Infants with severe congenital anomalies
2. Anticipated enteral fasting of more than 14 days
3. Infants who, in the opinion of the treating clinician, have no realistic prospect of survival

**Date of first enrolment**

01/09/2013

**Date of final enrolment**

28/09/2017

## Locations

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

Hull York Medical School and University of York

York

United Kingdom

YO10 5DD

## Sponsor information

**Organisation**

University of Oxford (UK)

**Sponsor details**

Clinical Trials and Research Governance

Joint Research Office

Block 60 Churchill Hospital

Old Road, Headington

Oxford

England

United Kingdom

OX3 7LE

**Sponsor type**

University/education

**ROR**

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

# Funder(s)

## Funder type

Government

## Funder Name

National Institute for Health Research (NIHR) Health Technology Assessment Programme (HTA)  
(ref: 10/57/14)

# 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

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/12/2018		Yes	No
<a href="#">Results article</a>	results	02/02/2019		Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No