

Rapid versus slow rate advancement of feeds for enterally fed extremely low birth weight infants $\leq 1000\text{g}$

Submission date 28/09/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 07/12/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 21/01/2019	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims?

The best way of feeding by injection has not been established in preterm infants especially those weighing less than 1000g. This is because uncertainty exists regarding when to initiate feeds and how fast feeds should be advanced. The uncertainty is based on studies which raised concerns that early and rapid feeding strategies may be cause an infection of the gut called Necrotising Enterocolitis (NEC).

The aim of the study is to establish how well commencing milk feeds at 24ml/kg on the day of birth and advancing feeds at 36ml/kg/d, in babies with a birth weight at or below 1000g will work.

Who can participate?

Infants weighing $\leq 1000\text{g}$ at birth can participate.

Infants cannot participate if any of the following is present:

1. Any congenital abnormalities which makes enteral feeding (via stomach or intestine) impossible and is life threatening
2. Any infants delivered outside of the centre where the study takes place

What does the study involve?

Infants will be randomly allocated to one of four groups:

1. Low volume initiation + slow advancement
2. Low volume initiation + rapid advancement
3. High volume initiation + slow advancement
4. High volume initiation + rapid advancement

Allocation to one the groups will also depend on weight ($<700\text{g}$ and $701-999\text{g}$) and gender.

What are the possible benefits and risks of participating?

Rapid advancement feeding strategies would improve growth and nutrition and potentially reduce infection rates. Fewer intravenous lines would be inserted. Hospital stays would become shorter.

As both feeding regimens are in routine use it is not expected that an unexpected adverse reaction suspected to be caused by one of the feeding regimens is likely to occur

Where is the study run from?

The study will be conducted in the neonatal unit at Groote Schuur Hospital in Cape Town, South Africa.

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

The study started recruiting on the 8 August 2011. We hope to recruit 200 patients over a period of 2 years.

Who is funding the study?

Incidental costs will be funded by the principal investigator

Who is the main contact?

Dr M Shukri Raban (principal investigator)

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

HREC REF 283/2011

Study information

Scientific Title

Rapid versus slow rate advancement of feeds for enterally fed extremely low birth weight infants $\leq 1000\text{g}$: a randomised controlled trial

Study objectives

Infants $\leq 1000\text{g}$ at the study site currently have their feeds initiated on day 1 at 4ml/kg/day and are advanced to 24ml/kg/day until they reach full enteral feeds at a volume of 150ml/kg , thereafter the feeds will be increased till a volume of 200ml/kg is reached. This usually takes ± 10 days. Additionally these infants will also receive FM85, multivitamins, 5% sodium chloride, phosphate sandoz and iron supplementation. The study aims to show that the intervention of initiating feeds at a high or low volume then advancing the feeds at 36ml/kg/d , results in better growth patterns as demonstrated in the time to attain a weight of 1500g but also in serial length and head circumference measurements, take fewer days to full enteral feeds, require fewer or no days of total parenteral nutrition and a potentially shorter hospital stay. The study also tests the hypothesis that fast feeding strategies will not increase the background incidence of necrotising enterocolitis (NEC) or mortality.

Ethics approval required

Old ethics approval format

Ethics approval(s)

University of Cape Town, Faculty of Health Sciences- Human Research Ethics Committee approved on 26/07/2011, ref: HREC 283/2011

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details below to request patient info sheet

Health condition(s) or problem(s) studied

Low birth weight

Interventions

Randomised into four groups

1. Low volume initiation + slow advancement
2. Low volume initiation + rapid advancement
3. High volume initiation + slow advancement
4. High volume initiation + rapid advancement

Low volume initiation: Feeding will be initiated on the first day with 4ml/kg of expressed human breast milk (EBM) or donor human breast milk (DEBM)

High volume initiation: Feeding will be initiated on the first day with 24ml/kg of EBM/DEBM

Slow advancement: On day 2 the infant will receive 12ml/kg/day of EBM/DEBM. Thereafter the feeds will be increased in increments of 24ml/kg/day until enteral feeds of 200ml/kg/day are attained. If the infant is randomised to the high initiation + slow advancement arm; Feeding will be initiated on the first day with 24ml/kg/d of EBM/DEBM, on day 2 the infant will receive 24ml/kg/d. Thereafter the feeds will be increased in increments of 24ml/kg/day until enteral feeds of 200ml/kg/day are attained.

Rapid advancement: After day 1, the feeds will be increased in increments of 36ml/kg/day until enteral feeds of 200ml/kg/day are attained.

Intervention Type

Supplement

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Multivitamins, 5% sodium chloride, phosphate, iron supplementation

Primary outcome measure

Time to attain 1500g weight

Secondary outcome measures

1. Clinical
 - 1.1. Time to regain birth weight
 - 1.2. Time to discharge
 - 1.3. Mortality
 - 1.4. Days nil by mouth
 - 1.5. Necrotising enterocolitis (NEC)
 - 1.6. Death before discharge
 - 1.7. Growth in head circumference to discharge
 - 1.8. Growth in length to discharge
 - 1.9. The need for total parenteral nutrition (TPN)
2. Health services resource utilisation
 - 2.1. Days of parenteral nutrition
 - 2.2. Time to death or discharge

Overall study start date

08/09/2011

Completion date

08/09/2013

Eligibility

Key inclusion criteria

All inborn infants less than or equal to 1000g

Participant type(s)

Patient

Age group

Neonate

Sex

Both

Target number of participants

200

Key exclusion criteria

1. All outborn infants
2. Congenital abnormalities which would preclude feeds or immediately life threatening

Date of first enrolment

08/09/2011

Date of final enrolment

08/09/2013

Locations

Countries of recruitment

South Africa

Study participating centre

30 Chukker Rd

Cape Town

South Africa

7780

Sponsor information

Organisation

University of Cape Town (South Africa)

Sponsor details

School of Child and Adolescent Health
Division: Neonatal Medicine
H46 OMB
Groote Schuur Hospital
Observatory
Cape Town
South Africa
7925

Sponsor type

University/education

Website

<http://www.scah.uct.ac.za/Neonatology.html>

ROR

<https://ror.org/03p74gp79>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded (South Africa)

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?
Results article	results	01/11/2016	21/01/2019	Yes	No