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Rapid versus slow rate advancement of feeds for enterally fed extremely low birth weight infants ≤1000g

Submission date
28/09/2011

Recruitment status
No longer recruiting

Registration date
07/12/2011

Overall study status
Completed

Last Edited
21/01/2019

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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 ≤1000g 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 (<700g and 701-999g) 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)
shukriraban@yahoo.co.uk

Contact information

Type(s)
Scientific

Contact name
Dr M Shukri Raban

Contact details
30 Chukker Rd
Kenwyn
Cape Town
South Africa
7780
+27 82 312 4819
shukriraban@yahoo.co.uk

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 ≤1000g: a randomised controlled trial

Study objectives
Infants ≤1000g 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. Ttime 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