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ADEPT - Abnormal Doppler Enteral Prescription Trial

Submission date 30/09/2004	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/09/2004	**Overall study status** Completed	
Last Edited 14/02/2014	**Condition category** Neonatal Diseases	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.action.org.uk/research_projects/grant/257/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

SP4006

Study information

Scientific Title
Randomised controlled trial of early versus late initiation of milk feeds for infants with absent or reversed end diastolic flow velocities (AREDFV) or cerebral redistribution

Acronym
ADEPT

Study objectives
The aim is to evaluate the effects of an 'early' enteral feeding regimen, starting milk feeds on day 2 after birth (between 24 and 48 hours of age) compared to one of 'late' introduction of enteral feeds, starting feeds on day 6 after birth (between 120 - 144 hours of age) in a group of babies identified as being at high risk for necrotising enterocolitis (NEC) and milk intolerance by antenatal Doppler studies.

Added 23/11/2007:
Please note that due to an extension in funding from Action Medical Research the anticipated end date of this trial has been extended to 31/12/2008. The previous end date of this trial was 05 /03/2008.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Oxfordshire Research Ethics Committee (REC) C gave approval on the 27th September 2005 (ref: 05/Q1606/121)

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 the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Nutrition

Interventions
Feeding of preterm infants after absent or reversed end-diastolic flow velocities (AREDFV). Babies will be randomly allocated to an 'early' or 'late' enteral feeding regimen. These will start milk feeds on day 2 and day 6 after birth, respectively.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Age in days at which full enteral feeding sustained for 72 hours was reached
2. Necrotising enterocolitis, stage I, II or III

Secondary outcome measures
1. Death before hospital discharge
2. Duration of hospital stay
3. Duration of intensive and high dependency care
4. Duration of parenteral nutrition
5. Change in Z score for weight and head circumference from birth to 36 weeks postmenstrual age and from birth to discharge
6. In continuous supplemental oxygen at 36 weeks post-menstrual age
7. Confirmed bacterial sepsis
8. Gastrointestinal perforation
9. Gastrointestinal surgery
10. Cholestasis (defined as greater than 25 µmol/l conjugated fraction of serum bilirubin)
11. Patent ductus arteriosus requiring pharmacological or surgical treatment
12. Type of milk at discharge
13. On oxygen therapy at discharge

This information is collected prior to the baby being discharged home.

Overall study start date
01/09/2005

Completion date
31/12/2008

Eligibility

Key inclusion criteria
Infants admitted to participating neonatal units and satisfying all of the following criteria may be recruited into the study:
1. Gestational age up to and including 34 weeks + 6 days
2. Antenatal ultrasound showing either:
2.1. Absent or reversed end diastolic flow velocities on at least 50% of the Doppler waveforms from the umbilical artery on at least one occasion during pregnancy, or

2.2. Cerebral redistribution, defined as occurring when both the umbilical artery pulsatility index is greater than the 95th centile and the middle cerebral artery pulsatility index is less that the 5th centile for gestational age
3. Small for gestational age
4. Postnatal age 20 - 48 hours

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
400 babies

Key exclusion criteria
Infants will be excluded if any of the following factors are present:
1. Major congenital abnormality including known chromosomal abnormality
2. Twin-twin transfusion
3. Intra-uterine transfusion or exchange transfusion
4. Rhesus iso-immunisation
5. Significant multi-organ failure prior to trial entry
6. Inotropic drug support prior to trial entry
7. Already received any enteral feeding

Date of first enrolment
01/09/2005

Date of final enrolment
31/12/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Consultant Neonatologist
Bristol
United Kingdom
BS10 5NB

Sponsor information

Organisation
University of Oxford (UK)

Sponsor details
University Offices
Wellington Square
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Sponsor type
University/education

Website
http://www.ox.ac.uk

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Charity

Funder Name
Action Medical Research (UK)

Alternative Name(s)
actionmedres, action medical research for children, AMR

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	02/10/2009		Yes	No
Results article	results	01/05/2012		Yes	No
Results article	results	01/01/2014		Yes	No