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ADEPT - Abnormal Doppler Enteral Prescription Trial

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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

Key secondary outcome(s))

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.

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

Healthy volunteers allowed
No

Age group
Neonate

Sex
All

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
United Kingdom

England

Study participating centre
Consultant Neonatologist
Bristol
United Kingdom
BS10 5NB

Sponsor information

Organisation
University of Oxford (UK)

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Charity

Funder Name
Action Medical Research (UK)

Alternative Name(s)

action medical research for children, actionmedres, The National Fund for Research into Crippling Diseases, AMR

Funding Body Type
Private sector organisation

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

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2012		Yes	No
Results article	results	01/01/2014		Yes	No
Protocol article	protocol	02/10/2009		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes