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Tolerance of milk feeds in preterm, very low birth-weight babies: the use of glycerine suppositories

Submission date 05/01/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 17/02/2006	**Overall study status** Completed	
Last Edited 16/01/2014	**Condition category** Neonatal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2005-000302-31

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
04/S0101/37 (EudraCT number 2005-000302-31)

Study information

Scientific Title

Study objectives
Does the use of regular glycerine suppositories shorten the time to first achievement of full enteral feeds in preterm, very low birth-weight infants?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Awaiting final approval

Study design
Prospective, open, randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Feeding problems related to prematurity

Interventions
Glycerine suppositories, control group will receive usual neonetal care following randomisation

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Glycerine suppositories

Primary outcome measure
Time to achieve first full enteral feeds

Secondary outcome measures
1. Number of episodes of abdominal distention
2. Oxygen requirements
3. Development of NEC
4. Episodes of sepsis
5. Growth

Overall study start date
06/02/2006

Completion date
06/02/2007

Eligibility

Key inclusion criteria
All preterm babies born at Wishaw General Hospital at less than 32 weeks gestation

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
28

Key exclusion criteria
Babies with any of the following will be excluded:
1. Major dysmorphic features
2. Any structural gastrointestinal anomaly present
3. Necrotising enterocolitis (NEC)
4. Perinatal hypoxic ischemia
5. Encephalopathy

Date of first enrolment
06/02/2006

Date of final enrolment
06/02/2007

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Wishaw General Hospital
Wishaw
United Kingdom
ML2 0DP

Sponsor information

Organisation
NHS Lanarkshire Primary Care Operating Division (UK)

Sponsor details
Strathclyde Hospital
Airbles road
Motherwell
United Kingdom
ML1 3BW

Sponsor type
Government

ROR
https://ror.org/049prb569

Funder(s)

Funder type
Government

Funder Name
NHS Lanarkshire Primary Care Operating Division 04/S0101/37

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	01/05/2011		Yes	No