

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
Registration date 17/02/2006	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 16/01/2014	Condition category Neonatal Diseases	☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

2005-000302-31

Protocol serial number

04/S0101/37 (EudraCT number)

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

Primary study design

Interventional

Study design

Prospective, open, randomised controlled trial

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Feeding problems related to prematurity

Interventions

Glycerine suppositories, control group will receive usual neonatal care following randomisation

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Glycerine suppositories

Primary outcome(s)

Time to achieve first full enteral feeds

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Neonate

Sex

All

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**

United Kingdom

Scotland

Study participating centre

Wishaw General Hospital

Wishaw

United Kingdom

ML2 0DP

Sponsor information**Organisation**

NHS Lanarkshire Primary Care Operating Division (UK)

ROR

<https://ror.org/049prb569>

Funder(s)

Funder type

Government

Funder Name

NHS Lanarkshire Primary Care Operating Division 04/S0101/37

Results and Publications

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