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

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

Plain English summary of protocol

Not provided at time of registration

# Contact information

Type(s)

Scientific

Contact name

Dr Samuel Ibhanesebhor

### Contact details

Wishaw General Hospital Netherton street Wishaw United Kingdom ML2 0DP

# 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