ISRCTN95873364 https://doi.org/10.1186/ISRCTN95873364

Safety of the varying concentrations of milk feeds with food additives and medications

Submission date	Recruitment status	[_] Prospectively registered
29/03/2016	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
08/04/2016	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
18/11/2021	Other	

Plain English summary of protocol

Background and study aims
Breastfeeding has been shown to be beneficial for babies, helping to protect them against diseases and providing all the nutrition they need for healthy growth. It is well known that certain substances can be passed from the mother to the baby via breast milk. If a mother has to take a medication, the medication is sometimes diluted with water, but studies have shown that this can raise the osmolality of breast milk, which can cause complications in the baby. Osmolality is the amount of a substance dissolved in a liquid. The aim of this study is to compare the changes in osmolality of 14 medications and other substances in breast milk.

Who can participate?
Women aged 28 to 41 who have delivered their baby at least three weeks early.

What does the study involve?
Women provide a sample of 60-80ml breast milk, expressed using a breast pump. The samples then have their osmolality (concentration) tested before a medication or fortifier is added. The osmolality is tested using a specialised machine called an osmometer. After the medication /fortifier has been added to the breast milk, the osmolality is then retested. This is then repeated four hours later.

What are the possible benefits and risks of participating?
There are no direct benefits or risks for participants taking part in this study.

Where is the study run from?
KK Women's and Children's Hospital (Singapore)

When is the study starting and how long is it expected to run for?
May 2014 to May 2015

Who is funding the study?
Paediatric Academic Clinical Program, KK Women’s and Children’s Hospital (Singapore)

Who is the main contact?
Dr Suresh Chandran

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Medications increasing osmolality and compromising the safety of enteral feeding in preterm infants

Study objectives
Hypothesis
The addition of commonly used medications to oral neonatal feeds increase the osmolality beyond that of the safety range as determined by the American Academy of Paediatrics (AAP).

Specific study aims:
1. To determine the osmolality of 15 commonly used medications prescribed in neonates
2. To determine the appropriate type and amount of diluent necessary to ensure osmolality of oral feeds remains within the safety range after the addition of medications
3. To evaluate the changes in osmolality of the medications in expressed breast milk and preterm formula after the addition of these 15 commonly used medications in neonatal care respectively and to explore if there is a correlation between osmolality and the amount of diluent added

4. To determine the changes of osmolality of expressed breast milk and preterm formula with time when medications are added

Ethics approval required
Old ethics approval format

Ethics approval(s)
Sing Health Centralised Institutional Review Board, 20/05/2014, ref: 2014/308/E

Study design
Cross-sectional laboratory-based study.

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Other

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
Osmolality of milk feeds

Interventions
Participants donate 60-80ml breast milk, which is collected using a breast pump. Pooled expressed breast milk (EBM) is stored in aliquots and is frozen at –5°C to –15°C. Before measuring the osmolality, the frozen EBM is thawed by transferring to the fridge (4°C) for at least 12 hours. Milk osmolality of each aliquot is measured three times at baseline, following which, fortifier and/or medications are added.

Additives added to dilutents:
1. Caffeine citrate (20mg/ml)
2. Folic acid (100mcg/ml)
3. Hydrochlorothiazide (5mg/ml)
4. Omeprazole (2mg/ml)
5. Phenobarbitone (10mg/ml)
6. Sodium phosphate (phosphate 0.52mmol/ml and sodium 0.85 mmol/ml)
7. Calcium glubionate (elemental calcium 115mg/5ml)
8. Domperidone suspension (1mg/ml)
9. Ibuprofen syrup (100mg/5ml)
10. Iron polymaltose drops (1ml = 50mg)
11. Multivitamin drops
12. Potassium dihydrogen phosphate (1mmol/1ml)

13. 20% sodium chloride (Na 3.4mmol/ml)
14. Ursodeoxycholic acid suspension (250mg/5ml)

The osmolality of medications and diluents was measured neat and in a combination of each medication with each diluent via the freezing point depressing method, utilizing an Advanced Micro-osmometer Model 3300 (Advanced Instruments, Inc. Two Technology Way, Norwood, MA 02062). The highest osmolality measurable by this method is 2000 mOsm/kg.

Intervention Type
Other

Primary outcome measure
Osmolality of expressed breast milk is measured using osmometer at baseline, when additives are added and 4 hours after additives are added.

Secondary outcome measures
No secondary outcome measures

Overall study start date
20/05/2014

Completion date
19/05/2015

Eligibility

Key inclusion criteria
1. Aged 28 to 41 years
2. Delivered their infants preterm (<37 weeks of gestation)
3. Willing to donate their breast milk

Participant type(s)
Other

Age group
Other

Sex
Female

Target number of participants
Nine mothers who volunterely donated breast milk

Key exclusion criteria
Mothers who do not want to participate due to personal reasons.

Date of first enrolment
20/05/2014

Date of final enrolment

31/08/2014

Locations

Countries of recruitment
Singapore

Study participating centre
KK Women's and Children's Hospital
100 Bukit Timah Road
-
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229899

Sponsor information

Organisation
Paediatric Academic Clinical Program

Sponsor details
KK Womens and Childrens Hospital
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Sponsor type
Research organisation

ROR
https://ror.org/01tgyzw49

Funder(s)

Funder type
Research organisation

Funder Name
Paediatric Academic Clinical Program, KK Women's and Children's Hospital

Results and Publications

Publication and dissemination plan
1. Poster presentation done at the Evidence based Neonatology Conference held in Philadelphia, USA - Sept 2015
2. Planned publication of study results within 3-6 months in a peer reviewed journal

Intention to publish date
31/12/2016

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		29/12/2016	18/11/2021	Yes	No