

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

Submission date 29/03/2016	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 08/04/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 18/11/2021	Condition category Other	<input type="checkbox"/> Individual participant data

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

Dr Suresh Chandran

Contact details

KK Womens and Childrens Hospital

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Additional identifiers

Protocol serial number

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

Study type(s)

Other

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 diluents:

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(s)

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

Key secondary outcome(s)

No secondary outcome measures

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

Healthy volunteers allowed

No

Age group

Other

Sex

Female

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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Singapore

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Sponsor information

Organisation

Paediatric Academic Clinical Program

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

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