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Comparing orange or apple juice to water during labour in women with mild gestational diabetes

Submission date
28/02/2023

Recruitment status
No longer recruiting

Registration date
06/03/2023

Overall study status
Completed

Last Edited
06/03/2023

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Gestational diabetes is very common, affecting about 20% of pregnancies. About 80-90% of gestational diabetes is mild and women need only pay attention to their diet to control their blood sugar. Drinking during labour is safe. Many women prefer to drink sugar (energy) containing beverages during labour. There are some data to suggest that drinking energy-containing beverages in labour or just before Caesarean birth may improve birth and recovery-related outcomes. This study aims to compare drinking beverages containing carbohydrates compared to plain water only during labour in women with mild gestational diabetes whose blood sugars are controlled by diet, to evaluate its impact on the baby's umbilical cord artery blood pH. The umbilical cord artery blood pH is an indicator of the baby's metabolic (general) well-being at birth.

Who can participate?
Labouring adult women who have gestational diabetes

What does the study involve?
Participants will be randomised to water or carbohydrate beverages (orange or apple juice) as oral fluids during their labour. The beverages will be given to women once they are in labour for them to drink, as much of and as often as they prefer. The primary outcome of the study is to evaluate the comparative effectiveness of these beverages on the baby's umbilical cord artery blood pH taken after delivery. The umbilical cord artery blood pH is an all-round indicator of baby wellbeing. In addition, a number of secondary mother and baby outcomes will also be evaluated including blood sugar in labour, time to delivery, mode of delivery, blood loss at delivery, mothers' satisfaction with their allocated beverage and baby outcomes like baby condition at birth (Apgar score), blood sugar after birth and admission to a baby ward.

What are the possible benefits and risks of participating?
The study expects to find that sugar-containing beverages (orange or apple juice) consumed during their labour by women with mild gestational diabetes that only needed diet to control, will not be harmful to the baby or the mother. Hence these women need not be restricted from

drinks with sugar in labour. It is plausible that sugar-containing beverages in providing energy compared to plain water may enhance women's labour.

The possible benefits of participation are that drinking juice (energy-containing fluid) during labour may improve participants' labour performance. Fewer issues may be associated with low blood sugar during labour for these women. Major complications are not anticipated. Juice drinks may cause blood sugar to increase beyond the normal range and necessitate additional blood sugar monitoring or treatment measures to achieve control. However, we do not expect the baby to be affected by these acute changes if indeed they occur.

Where is the study run from?
Universiti Malaya Medical Center (Malaysia)

When is the study starting and how long is it expected to run for?
October 2022 to April 2024

Who is funding the study?
Universiti Malaya Medical Center (Malaysia)

Who is the main contact?
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Carbohydrate containing beverage compared to water during labour in women with gestational diabetes mellitus: A randomised controlled trial

Study objectives

We hypothesize that carbohydrate beverages during labour for women with gestational diabetes on diet control only will not impair (non-inferior) neonatal cord artery blood pH

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 23/02/2023, Medical Research and Ethics Committee (University Malaya Medical Centre, Kuala Lumpur, Malaysia; +603 7949 3209, +603 7949 2251; ummc-mrec@ummc.edu.my), ref: 20221228-11883

Study design
Randomized controlled trial

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Labouring women with gestational diabetes mellitus on diet control only

Interventions
Participants will be randomised to water or carbohydrate beverages (orange or apple juice) as oral fluids during their labour.

Method of randomization
Randomization is done by opening the lowest number, sealed and opaque envelope that is available, assigned in strict order to the newest recruit. The randomization sequence will be generated using a random number generator in random blocks of 4 or 8 sequences, generated by an investigator who is not involved in recruitment and placed within the envelopes. Randomly allocated intervention of drinking carbohydrate drinks or water only will only be revealed after the opening of the numbered envelope following written consent to participate.

Intervention provider
The intervention providers are medical residents or postnatal ward nurses or midwives in our centre who will provide the appropriate drink as allocated for women to consume at their own pace

Modes of delivery
The allocated drink will be delivered by hand to the participants

Location of intervention
Labour ward, Universiti Malaya Medical Centre, Kuala Lumpur

Intervention Type
Supplement

Primary outcome(s)

Umbilical cord arterial blood pH value measured using hospital electronic medical records at hospital discharge

Key secondary outcome(s))
Neonatal outcome (measured using hospital electronic medical records at hospital discharge):
1. Umbilical cord arterial blood base excess
2. APGAR score at 1 minute and 5 minutes
3. Newborn blood sugar within 4 hours of birth
4. Birth weight
5. Neonatal admission (and indication)
6. Neonatal hypoglycemia (clinical diagnosis)
7. Birth trauma
8. Hypoxic-ischemic encephalopathy
9. Sepsis

Maternal outcome (measured using hospital electronic medical records at hospital discharge):
1. Intrapartum capillary blood glucose
2. Use of insulin infusion in labour
3. Vomiting in labour
4. Epidural analgesia in labour
5. Time to delivery
6. Mode of delivery
7. Perineal injury
8. Estimated blood loss
9. Intensive care unit admission

Completion date
30/04/2024

Eligibility

Key inclusion criteria
1. Gestational diabetes mellitus on diet control only (GDMA1)
2. In active labour (cervical dilatation 3cm and contraction 3 in 10 minutes)
3. Term (gestational age 37 weeks)
4. Aged 18 years old and over
5. Single baby
6. Baby is in head down position (cephalic presentation)
7. Baby’s condition (cardiotocograph) is reassuring

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit

18 years

Sex
Female

Key exclusion criteria
1. On antiglycaemic drug for diabetes mellitus
2. BMI > 40
3. Preeclampsia
4. Known major fetal malformations
5. Evidence of chorioamnionitis or other maternal infection
6. Medical instruction forbidding oral intake
7. Contraindication for vaginal birth

Date of first enrolment
13/03/2023

Date of final enrolment
01/04/2024

Locations

Countries of recruitment
Malaysia

Study participating centre
Universiti Malaya Medical Center
University Malaya
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Sponsor information

Organisation
University Malaya Medical Centre

ROR
https://ror.org/00vkrxq08

Funder(s)

Funder type
University/education

Funder Name
Universiti Malaya

Alternative Name(s)
University of Malaya, University Malaya, Malayan University, King Edward VII College of Medicine, Raffles College, University of Malaya in Singapore, , , , UM

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Malaysia

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available later

IPD sharing plan summary
Data sharing statement to be made available at a later date