

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

<b>Submission date</b> 28/02/2023	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 06/03/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 06/03/2023	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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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## Contact information

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**Additional identifiers****EudraCT/CTIS number**

Nil known

**IRAS number****ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

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

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Other

**Participant information sheet**

No available in web format, please use contact details to request a participant information sheet.

**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 measure

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

#### Secondary outcome measures

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

#### Overall study start date

01/10/2022

#### 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

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Female

**Target number of participants**

128 participants

**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

Jalan Profesor Diraja Ungku Aziz

Lembah Pantai

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# Sponsor information

## Organisation

University Malaya Medical Centre

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## Sponsor type

Hospital/treatment centre

## Website

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## 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, UM

## Funding Body Type

Government organisation

## Funding Body Subtype

Universities (academic only)

## Location

Malaysia

# Results and Publications

## Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

## Intention to publish date

01/12/2024

## 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