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Comparison of the effect of antenatal dexamethasone and betamethasone on blood sugar control in diet-controlled gestational diabetics

Submission date
18/01/2021

Recruitment status
No longer recruiting

Registration date
21/01/2021

Overall study status
Completed

Last Edited
04/02/2021

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
Steroids are given to pregnant women to reduce the risks to a baby who may be born prematurely for any reason. They are given commonly in pregnancy because premature delivery is still a continuing major problem. These steroids are most effective if it is given to the mother at least 24 hours before the baby is born and their effect lasts for up to a week. They also cause the mother's blood sugar level to rise, and this effect of the drug can last up to 5 days. The different regimes of steroids (dexamethasone or betamethasone) may have different effects on the pregnant woman's blood sugar levels. High blood sugar level for prolonged periods of time (as in patients with diabetes) may cause problems for the pregnancy and the baby, and the short-term high blood sugar levels caused by giving this medication may have a significant effect on the pregnancy. The aim of this study is to compare any differences in the rise in blood sugar level between the two different kinds of steroids (dexamethasone and betamethasone).

Who can participate?
Patients aged over 18, between 24 and 37 weeks of pregnancy, carrying only one baby, who have high blood sugar in pregnancy (gestational diabetes), are not on any medication, and are controlling their blood sugar level with only lifestyle and diet modifications.

What does the study involve?
The effect of the two different kinds of steroid (dexamethasone and betamethasone) on blood sugar levels will be compared. Half of the participants will be given dexamethasone (four doses 12 hours apart), and the other half will be given betamethasone (two doses 24 hours apart). The pregnant mother's blood sugar level will be tested at six different times of the day, before and 2 hours after their three main meals (breakfast, lunch, and dinner) for a total of 3 days (72 hours) after the first dose of the drug has been given.

What are the possible benefits and risks of participating?
Steroids will be given to patients who are at risk of delivering prematurely, and the drugs being

used in this study may provide protection for the baby against the risks of premature birth. One of the risks of participating in this study would be a significant increase in the already diabetic mother's blood sugar levels, that may need the use of medications (such as metformin or insulin) to control the levels. Participating in this study will ensure that the blood sugar levels for the participants are monitored sufficiently. Those patients who have a rise in blood sugar levels more than the normal range, and in need of medication to treat the high levels of blood sugar, will be given the treatment promptly and as needed.

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

When is the study starting and how long is it expected to run for?
April 2020 to December 2023

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

Who is the main contact?
1. Dr Jesrine Hong Gek Shan
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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
A randomized controlled trial of antenatal dexamethasone versus betamethasone on glycemic control in diet-controlled gestational diabetics

Acronym
ANDEB

Study objectives
The 4 x 6 mg 12-hourly antenatal dexamethasone regimen compared with 2 x 12 mg 24-hourly antenatal betamethasone would result in fewer hyperglycemic episodes in the first and second 24 hours.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 29/04/2020, Medical Research Ethics Committee, University of Malaya Medical Center (UMMC-MREC Secretariat Office , Level 2, Kompleks Pendidikan Sains Kejururawatan, University of Malaya Medical Centre, Lembah Pantai, 59100 Kuala Lumpur, Malaysia; +60 (0)3 7949 3209/ 2251; ummc-mrec@ummc.edu.my), ref: 2020212-8284

Study design
Interventional open-labelled single-centre prospective randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Gestational diabetes mellitus

Interventions
Eligible women who are about to receive antenatal corticosteroids will be approached to participate. Participants will be randomized to either 4 x 6 mg 12-hourly doses of intramuscular dexamethasone or 2 x 12 mg 24-hourly doses of intramuscular betamethasone. Randomization

will be on 1 to 1 ratio by opening the lowest numbered available, sealed and opaque envelope, prepared based on a computer-generated random sequence (using random.org) in random blocks of 4 or 8 by a co-investigator who is not involved in the trial recruitment.

Participants randomized to four doses of 6 mg dexamethasone will receive their first dose as soon as practicable with the second, third and fourth 6mg doses at 12, 24 and 36 hours to complete the course if not delivered. Participants randomized to two doses of 12 mg betamethasone will also receive their first dose as soon as practicable with the second dose given at 24 hours if not delivered.

All participants will be supplied with the necessary materials for self-monitoring of their blood sugar profiles, starting from the baseline measurement at recruitment. They will be instructed to perform their first trial blood sugar reading before their next meal or 2 hours after their last meal (2 hours is taken from the end of the meal). Participants will then continue monitoring their blood sugar values prior to and 2 hours post the three main meals (breakfast, lunch, and dinner) for 3 days (to obtain a total of 18 readings) if they have not delivered and will record the values on their record forms. Participants will be instructed to continue with their usual diet as advised when they are first diagnosed as GDM. Participants will be allowed to take home the record form if discharged before completing their blood sugar profile record for three consecutive days. Participants who are discharged from the hospital will be instructed to contact the investigator immediately through the provided contact number if their blood sugar reading is ≥11 mmol/l.

The record forms will be obtained from the participant after completion of blood sugar profile monitoring or earlier if delivered. Satisfaction score (by the Numerical Rating Scale, NRS 0 to 10, higher score, greater satisfaction) on their allocated antenatal corticosteroid regimen will be obtained after 3 days of monitoring or as soon as possible after delivery if it occurs sooner.

The participants' and the newborns' hospital records will be retrieved after delivery and specified secondary outcomes of the study will be transcribed onto the case record form.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Dexamethasone, betamethasone

Primary outcome measure
1. Hyperglycemia episodes in the first 24 hours following administration of antenatal corticosteroids, measured by point of care capillary blood glucose monitoring system at six points (pre and post breakfast, lunch and dinner) . Hyperglycemia is defined as pre-meal blood glucose level of more than 5.3 mmol/l and 2 hours postprandial/meal blood glucose of more than 6.7 mmol/l
2. Hyperglycemia episodes in the second 24 hours following administration of antenatal corticosteroids, by measuring point of care capillary blood glucose at points 7-12

Secondary outcome measures

1. Need for an anti-glycaemic agent (metformin or insulin), as indicated by capillary blood glucose levels for the duration of monitoring
2. Maternal outcomes assessed by reviewing patient's notes after delivery:
2.1. Mode of delivery
2.2. Estimated blood loss during delivery
3. Neonatal outcome assessed by reviewing patient's and newborn's notes after delivery:
3.1. Birth weight
3.2. Umbilical cord arterial pH at birth
3.3. Apgar score at first and fifth minute of life
3.4. Neonatal admission to special care nursery or neonatal intensive care
4. Patient satisfaction with their allocated antenatal dexamethasone or betamethasone regime measured using numerical rating score (NRS) score after 3 days of monitoring or as soon as possible after delivery if it occurs sooner

Overall study start date
01/04/2020

Completion date
31/12/2023

Eligibility

Key inclusion criteria
1. Gestational diabetes adequately controlled by lifestyle modification (gestational diabetes mellitus was defined as 75 g oral glucose tolerance test (OGTT) fasting blood glucose ≥5.1 mmol /l and/or 2 hours post-prandial glucose ≥7.8 mmol/l in pregnant women without prior history of hyperglycemia based on Malaysian National Clinical Practice Guideline diagnostic thresholds
2. Gestational age 24-37 weeks
3. Age ≥18 years old
4. Singleton pregnancy

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
150

Key exclusion criteria
1. Patients on anti-glycemic agent
2. Baseline (at recruitment) capillary blood glucose level ≥11 mmol/l

3. Active labor or having a high likelihood to deliver within the next 24 hours
4. Suspected chorioamnionitis, suspected maternal or fetal infection
5. On beta-sympathomimetic agent tocolysis
6. On oral intake restriction in anticipation of imminent (within next 24 hours) Cesarean birth

Date of first enrolment
01/02/2021

Date of final enrolment
01/02/2023

Locations

Countries of recruitment
Malaysia

Study participating centre
University Malaya Medical Center
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Sponsor type
Hospital/treatment centre

Funder(s)

Funder type

Hospital/treatment centre

Funder Name
University of Malaya Medical Center

Results and Publications

Publication and dissemination plan
1. Additional documents will be available
2. Planned publication in a high-impact peer-reviewed journal

Intention to publish date
31/12/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Jesrine Hong Gek Shan (jesrine@um.edu.my; jesrine@ummc.edu.my).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			04/02/2021	No	Yes