ISRCTN16613220 https://doi.org/10.1186/ISRCTN16613220

Is there a difference between 2 doses of 12 mg of dexamethasone given 12 hours apart compared with 4 doses of 6 mg dexamethasone given 12 hours apart in terms of the dosing regimen's impact on causing high blood sugar in the mother when dexamethasone is given to minimise risk of prematurity complications?

Submission date
25/01/2018

Recruitment status
No longer recruiting

Registration date
13/02/2018

Overall study status
Completed

Last Edited
18/01/2021

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Dexamethasone is a type of medication that can be given to pregnant women who are at risk of delivering their babies early to help improve either baby's health. Giving dexamethasone to the mother while she is still pregnant in order to improve the baby's maturity are usually administered 12 mg for 2 doses 12 hours apart or 6 mg for 4 doses 12 hours apart in contemporary practice. Both regimens are considered effective in helping the baby. However, this medication can cause the mother's blood sugar level to go up, an effect which may last up to 5 days. High maternal blood sugar level can slow the baby's lung maturation undermining the positive impact the medication can have on the baby. It is not currently known which antenatal dexamethasone regimen of 4 doses has a better impact on maternal blood glucose levels over the 3 days following the start of dexamethasone administration. A lower individual dose of 6 mg spread out over 36 hours may have a less severe impact on pushing maternal blood sugar level up then a 12 mg spread out over 12 hours. The aim of this study is to evaluate the impact of the two dexamethasone regimens on episodes of high maternal blood glucose.

Who can participate?
Women aged 18 and older who have mild gestational diabetes who are planned to use dexamethasone.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive 2 doses of 12 mg of dexamethasone 12 hours apart, given to them in an injection to a muscle.

Those in the second group receive 4 doses of 6mg of dexamethasone 12 hours apart, given in an injection to a muscle. Participants monitor their blood sugar level themselves six times per day (before and 2 hours after breakfast, lunch and dinner) for the three days after their injections. The outcomes of the births are collected.

What are the possible benefits and risks of participating?
There are no major benefits or risks anticipated to either mother or baby from the interventions.

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

When is the study starting and how long is it expected to run for?
January 2018 to November 2019

Who is funding the study?
Department of Obstetrics and Gynaecology, University Malaya (Malaysia)

Who is the main contact?
1. Professor Tan Peng Chiong (Scientific)
2. Dr Nuraini Sukarna (Scientific)

Contact information

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
MREC 201813-3

Study information

Scientific Title
Antenatal dexamethasone regimen in mild gestational diabetes: A Randomized controlled trial

Study objectives
The aim of this study is to show that a regimen 4 doses of 6 mg of dexamethasone compared with 2 doses of 12 mg dexamethasone every 12 hours causes less hyperglycaemia in mild gestational diabetes mellitus.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Medical Research & Ethics Committee, University Malaya Medical Center, 17/1/2018, ref: no 201813-3

Study design
Randomised clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Women with mild gestational diabetes mellitus between 24-38 weeks receiving antenatal dexamethasone for improvement of neonatal outcome.

Interventions

Randomisation sequence is generated in blocks of 4 or 8 by an investigator using random.org by an investigator not involved in recruitment. Randomisation is effected by the opening of sealed numbered opaques which contain the allocation of intervention.

Participants are randomly allocated to receive either

1. Two doses of 12 mg of dexamethasone administered intramuscularly 12 hours apart (cumulative dose 24 mg of dexamethasone; duration of intervention 12 hours)
or
2. Four doses of 6 mg of dexamethasone administered intramuscularly 12 hours apart (cumulative dose 24 mg of dexamethasone; duration of intervention 36 hours)

Participants are followed up with self monitoring of blood glucose (SMBG) using a personal glucometer 6 times per day (before and 2 hours after breakfast, lunch and dinner) for the three days (or up to delivery whichever occurs sooner) following initiation of dexamethasone injections.

Secondary outcomes includes maternal and neonatal delivery outcomes extracted from hospital records.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Dexamethasone

Primary outcome measure

The number of Hyperglycaemia episodes is measured using the self-monitoring of blood glucose (SMBG) pre and post main meals following administration of antenatal dexamethasone at six time points (first 24 hours).

Secondary outcome measures

1. Hyperglycaemia episodes in the second 24 hours after administration of antenatal dexamethasone is measured using self-monitoring of blood glucose (SMBG) pre and post main meals following administration of antenatal dexamethasone at six time points (second 24 hours)
2. Hyperglycaemia episodes in the third 24 hours after administration of antenatal dexamethasone is measured using self-monitoring of blood glucose (SMBG) pre and post main meals following administration of antenatal dexamethasone at six time points (second 24 hours)
3. Need for hypoglycaemic agent (metformin or other) is extracted from hospital records
4. Neonatal outcomes are assessed by reviewing patient and baby notes after delivery including:
4.1. Birth weight
4.2. Umbilical cord arterial pH at birth
4.3. Apgar score at 1st and 5th minute of life/birth

4.4. Special care nursery/neonatal intensive care unit admission during birth admission
5. Maternal outcomes are assessed by reviewing patient's notes after delivery including:
5.1. Mode of delivery
5.2. Estimated blood loss during delivery
6. Patient satisfaction score with allocated antenatal dexamethasone regimen is measured using a Visual Numerical Rating Scale (scored 0 to 10, higher score greater satisfaction) after the third day of SMBG or just after delivery if this occurs sooner

Overall study start date
11/01/2018

Completion date
01/10/2018

Eligibility

Key inclusion criteria
1. All antenatal cases with mild gestational diabetes mellitus between 24-38 weeks who are planned for antenatal dexamethasone for improvement of neonatal outcome. Gestational diabetes mellitus defined as 75 g oral glucose tolerance test (OGTT) of fasting blood glucose ≥ 5.1 mmol/l or a 2 hours post prandial glucose ≥ 7.8 mmol/l (American Diabetes Association 2016 guidelines). A "mild case of gestational diabetes" is defined as a patient adequately controlled glycaemic status without the for need oral hypoglycaemic agent or insulin.
2. Age more than 18 years old
3. Singleton pregnancy
4. Viable pregnancy

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
60

Total final enrolment
60

Key exclusion criteria
1. Patients on hypoglycaemic agent or insulin
2. Pre-existing Type 1 or Type 2 diabetes mellitus
3. Baseline capillary blood glucose level more than 11mmol/L (at recruitment)
4. Patients in active labour or likely to deliver within the next 24 hours after administration of

antenatal dexamethasone
5. Evidence of chorioamnionitis or other maternal or fetal infection
6. Patients on terbutaline or other beta-mimetic agents
7. Diet restricted in anticipation of imminent Caesarean birth

Date of first enrolment
15/02/2018

Date of final enrolment
30/08/2018

Locations

Countries of recruitment
Malaysia

Study participating centre
University Malaya Medical Center
University Malaya Medical Centre
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Sponsor information

Organisation
University Malaya

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Sponsor type
University/education

ROR
https://ror.org/00vkrxq08

Funder(s)

Funder type
University/education

Funder Name
Department of Obstetrics and Gynaecology, University Malaya

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.Study protocol, statistical analysis plan, other are not available.

Intention to publish date
30/06/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Professor Peng Chiong Tan, Department of Obstetrics and Gynaecology Faculty of Medicine
University Malaya pctan@um.edu.my. Participant level data can be made available 2 years after trial publication subject to ethical board approval.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2021	18/01/2021	Yes	No