UNIVERSITY OF MALAYA MEDICAL CENTRE

PARTICIPANT INFORMATION SHEET

Study Title: Randomized Controlled Trial of Antenatal Dexamethasone Versus Betamethasone on Glycemic Control in Diet Controlled Gestational Diabetics

Version No: 3.0

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We would like to invite you to take part in a research study. Before you decide whether to participate, you need to understand why the research is being done and what it would involve. Please take time to read the following information carefully; talk to others about the study if you wish.

Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Introduction:

Steroids are given to minimize prematurity related effects to the baby to women considered to be at imminent risk of a premature birth (e.g. preterm delivery or elective Caesarean up to 37 weeks). The beneficial effect of the steroids to the newborn is at its maximum if administered to the mother at least 24 hours before the birth and lasts about one week. Steroids causes the mother's blood sugar level to go up. This effect can last up to 5 days. Different regimes of steroids (dexamethasone or betamethasone) may have different blood sugar effect. Monitoring of blood sugar will allow us to identify the differences and provide treatment if needed. High blood sugar level for a prolonged period of time (as in diabetes) may cause problems for pregnancy and baby.

1. What is the purpose of this study?

To show that dexamethasone causes less increase in blood sugar level as compared with betamethasone.

2. Why is this study important?

Steroids is commonly given in pregnancy because premature delivery is a continuing major problem. Although its impact through causing short term high blood sugar level is not fully known, it may be significant. The cost of betamethasone is much higher than dexamethasone.

3. What type of study is this?

Randomized clinical trial.

4. What is the procedure that is being tested? (If applicable)

Not applicable.

5. Does the investigatory product contain cultural sensitive ingredients eg: bovine or porcine? (if applicable)

Dexamethasone and betamethasone are synthetic corticosteroids that do not contain cultural sensitive ingredients such as bovine or porcine.

6. Why have I been invited to participate in this study?

Steroids e.g. dexamethasone or betamethasone is required for your treatment and you fulfil the inclusion criteria of this study.

- Pregnancy between 24-37 weeks
- Age 18 years or older
- Carrying one baby only

7. Who should not participate in the study?

- If you are already on hypoglycemic agent (e.g. metformin, insulin).
- In active labor or may deliver within the next 24 hours
- Evidence of infection
- On terbutaline or other beta- mimetic agents
- On diet restriction in anticipation of imminent Caesarean birth

8. Can I refuse to take part in the study?

Yes. If you choose not to take part, your care will not be affected in any way.

9. What will happen to me if I take part?

If you have been planned for administration of steroids and you fulfil the inclusion criteria as listed below, you will be randomly allocated to be given dexamethasone or betamethasone. Your blood sugar level will be taken at recruitment, and you will be taught to self-check your pre meal and 2 hours post meal blood sugar level (6 times a day) for the next 3 consecutive days. You will be provided with all the necessary equipment and a diary to record down your blood glucose levels, and your satisfaction with monitoring and treatment.

You should continue on your usual diet. You should stop glucose monitoring at delivery should that happen within the 1-day study period. If you notice your blood sugar level is unacceptably high more than 11mmol/L, immediately contact the investigator.

10. How long will I be involved in this study?

For 3 days after receiving steroids for monitoring of blood sugar level, and satisfaction scoring with the monitoring and treatment. Information about your delivery will be collected from our hospital records. If our records are incomplete or you deliver elsewhere and we think you can help, we will contact you.

11. What are the possible disadvantages and risks?

Steroids causes the mother's blood sugar level to go up. This effect can last up to 5 days. Monitoring of blood sugar will allow us to identify the high blood sugar level and provide treatment if needed.

12. What are the possible benefits to me?

Due to the blood sugar monitoring, any high blood sugar level will be detected and treated accordingly.

13. Who will have access to my medical records and research data?

Only the investigators and clinicians in charge.

14. Will my records/data be kept confidential?

Yes.

15. What will happen to any samples I give? (If applicable)

Not applicable.

16. What will happen if I don't want to carry on with the study?

You can do so at any time without having to provide any reason and your care will also not be affected in any way.

17. What if relevant new information about the procedure/ drug/ intervention becomes available? (If applicable)

Not applicable.

18. What happens when the research study stops? (If applicable)

The treatment and management for you continue as per protocol.

19. What will happen to the results of the research study?

The results will be collected, analyzed and interpreted.

20. Will I receive compensation for participating in this study?

No payment or compensation will be given.

21. Who funds this study?

Research grant.

22. Who should I contact if I have additional questions/problems during the course of the study?

Name of investigator: Dr. Fathimath Shamaa Shareef
Affiliation: University Malaya Medical Centre
Telephone number: 013-9208395

23. Who should I contact if I am unhappy with how the study is being conducted?

Medical Research Ethics Committee
University of Malaya Medical Centre
Telephone number: 03-7949 3209/2251