

**Participant Information Sheet/Consent Form**

The Royal Brisbane and Women’s Hospital

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| **Title** | Pharmacokinetic profile and breastmilk excretion of sugammadex in pregnant women |
| **Short Title** | Sugammadex in pregnant women |
| **HREC Number** | HREC/2021/QRBW/74517 |
| **Protocol Number** | Version 1 |
| **Sponsor** | Department of Anaesthesia and Perioperative Medicine, RBWH |
| **Principal Investigator** | Dr Anthony Hodge |
| **Associate Investigator** | Professor Jason RobertsAssociate Professor Victoria EleyDr Angela TognoliniDr Steven Wallis |
| **Location**  | The Royal Brisbane and Women’s Hospital |

**Part 1 What does my participation involve?**

1. **Introduction**

You are invited to take part in this research project. This is because your anaesthetist has determined that the safest way to have your baby via caesarean delivery is to be under a general anaesthetic. The research project aims to better understand optimal dosing of the medication sugammadex and if it is excreted in breastmilk. Sugammadex is a medication that is currently used in pregnant patients. We would like to find out how the physiological changes of pregnancy change the way the body metabolises and excretes this medication) and if it is found in the breastmilk afterwards.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and research involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don’t understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or local doctor.

Participation in this research is voluntary. If you don’t wish to take part, you don’t have to. You will receive the best possible care whether or not you take part.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

* Understand what you have read
* Consent to the research project
* Consent to the tests and research that are described
* Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

1. **What is the purpose of this research?**

Sugammadex is an anaesthetic medication that gained regulatory approval in 2008 in Australia and is used for restoring muscle function following a general anaesthetic. All medications have to be approved in this way by the Australian Federal Government.

Even though anaesthetists have used sugammadex in pregnant women for some years now, there is no specific information on how it is metabolised and excreted in pregnancy. Although we think that very little of it is excreted in breastmilk, this has not been studied. Many studies have been undertaken of sugammadex use in children, older people and people with kidney disease. But not for pregnant women.

We would like to find out how the physiological changes of pregnancy change the way the body metabolises and excretes this medication and if it is found in the breastmilk afterwards. This may help us tailor the dose especially for pregnant women.

This research has been initiated by the study doctor, Dr Anthony Hodge.

This research is being funded by internal departmental sources*.*

1. **What does participation in this research involve?**

You will be prepared for surgery as per normal. There will be no change to your surgical procedure or the care you receive during your admission to hospital at the Royal Brisbane and Women’s Hospital.

There will be no change to the anaesthetic plan that you would receive if otherwise attending the Royal Brisbane and Women’s Hospital for your procedure. You will have a discussion with your anaesthetist about your anaesthetic and pain relief. Before any research begins you will need to understand and sign the consent forms.

Your preoperative care will occur as normal. On the day of your caesarean section, your anaesthetic team will place an intravenous cannula into your arm to provide fluids and medications to facilitate your caesarean delivery. A second intravenous cannula will be inserted by the anaesthetist, preferably in your elbow which will be used for blood sampling only. The second intravenous cannula will be removed from your elbow when you are ready to leave the recovery area. Removal causes minimal discomfort.

Your anaesthetist will provide general anaesthesia (putting you to sleep). Once you are asleep, you will be administered a muscle relaxant called rocuronium to allow a breathing tube to be placed. This is standard practice for all patients having a caesarean delivery under general anaesthesia. During your surgery, the anaesthetic team will monitor your vital signs and muscle function which is standard care for all patients having a general anaesthetic. At the completion of surgery, sugammadex will be administered to restore muscle function back to normal. After receiving a dose of sugammadex, a dedicated research nurse will take multiple samples of blood from the previously inserted intravenous cannula over the course of the next 60 minutes whilst you recover from surgery. A further blood sample will be taken at 6 and 24 hours post your surgery. Approximately 10 samples will be taken from the cannula, which is less than 50 mL (approximately 10 teaspoons) in total. The blood samples will be sent to the laboratory to measure blood levels of sugammadex.

Prior to your caesarean delivery, you will have an indwelling catheter placed to drain your bladder before surgery. This is standard practice for all patients having a caesarean delivery. The research team will collect urine from this catheter following your caesarean delivery for up to 6 hours after your surgery.

While you are in the recovery room/area after your general anaesthetic, the Research Nurse with the assistance of the attending midwife will assist you with breastfeeding. At this time, we would ask that you provide us with a tiny sample of breast milk – around 0.2-0.4 of a mL. That is about the amount that would cover a 5-cent piece and it can be collected in a tiny syringe. A further small sample of breast milk (0.2-0.4 mL) will be collected at 6-hours post your surgery.

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids study doctors or participants jumping to conclusions.

There are no additional costs associated with participating in this research project, nor will you be paid. All medical care required as part of the research project will be provided to you free of charge.

It is desirable that your local doctor be advised of your decision to participate in this research project. If you have a local doctor, we strongly recommend that you inform them of your participation in this research project.

**4 What do I have to do?**

You do not have to do anything different for this study as your clinical care will continue as normal. The only difference is that prior to your caesarean section you will have an additional intravenous cannula placed in your arm by your anaesthetist which will be used to take a total of 45-50mL of blood during your surgery (approximately 10 teaspoons).

**5 Other relevant information about the research project**

We are expecting 15 pregnant women to take part in this project, all at The Royal Brisbane and Women’s Hospital.

As part of this project, the research team will talk to you about your medical and obstetric history including the history of your current pregnancy and the reason your obstetric team has advised for you to have a caesarean delivery. We will record information about you including your age, number of previous pregnancies, gestational age at delivery, singleton or twins/triplet pregnancy, height, weight (within 2 weeks of surgery), BMI (based on the weight within 2 weeks), other medical conditions, pregnancy-related conditions, study number and medical record number. The research team will require access to your medical records including antenatal blood results as part of the project. The research team will only gather information that is relevant to the research project and no identifying data will be recorded long-term for this project.

**6 Do I have to take part in this research project?**

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage, up until the point where you are under anaesthesia (and asleep). Following your caesarean delivery, you are free to withdraw at any time in the post-operative period.

If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with The Royal Brisbane and Women’s Hospital.

**7 What are the alternatives to participation?**

You do not have to take part in this research project to receive treatment at this hospital. If you decide to participate, you will receive sugammadex at the completion of your caesarean delivery to allow return of muscle function.

If you choose not to participate in this research project, you may still be administered sugammadex as part of your care because it is commonly used by anaesthetists in this hospital. The alternative medication to sugammadex is called neostigmine and has traditionally been used as a reversal agent to restore muscle function at the end of surgery. Neostigmine works in a different way to sugammadex and cannot be used to reverse high doses of muscle relaxants which are commonly required to facilitate caesarean delivery. If you choose not to participate in this project you will receive either sugammadex or neostigmine at the end of your surgery at the discretion of your treating anaesthetist.

You can also discuss the options with your local doctor,before you decide whether or not to take part in this research project.

**8 What are the possible benefits of taking part?**

There will be no clear benefit to you personally from your participation in this research, however, knowledge gained from this research will assist us in treating other patients in the future.

**9 What are the possible risks and disadvantages of taking part?**

The risks of taking part in the study are the same as those faced by any patient receiving a general anaesthetic. Your anaesthetist will discuss these with you prior to your surgery.

All medications administered as part of a general anaesthetic can have potential adverse side effects. If you choose to participate in this study, you will be administered medications that are usually administered to facilitate caesarean delivery under general anaesthesia. The study medication sugammadex is commonly administered to facilitate general anaesthesia in pregnant patients. Like all other medications, there are potential adverse reactions associated with sugammadex. Your study doctor will be looking out for side effects.

The study medication sugammadex, will be administered to you at the end of your caesarean after your baby has been born and there will be no chance that the medication will transfer by the placenta to your baby. The current information on sugammadex and breastfeeding is limited. However oral absorption of these types of medications is generally low and no effect on the suckling child is anticipated following a single dose to the breast-feeding woman.

An additional intravenous cannula will be required to be placed by your treating anaesthetist which may cause some discomfort, bruising, minor infection or bleeding. If this happens, it can be easily treated. If you decide to participate, you will have an increased amount of blood samples taken. However, these risks are very minimal. We will take approximately 10 samples from your cannula, which will be less than a total of 50 mL (approximately 10 teaspoons) of blood. This is a small amount and will not result in any side effects or complications.

There will be an extra research staff member present during your anaesthetic and surgery. If you become upset or distressed as a result of your participation in the research, the study doctor will be able to arrange for counselling or other appropriate support. Any counselling or support will be provided by qualified staff who are not members of the research project team. This counselling will be provided free of charge.

**10 What will happen to my test samples?**

Samples of your blood and breast milk obtained for the purpose of this research project will be de-identified and stored in a monitored, locked freezer. These blood tests will be transferred to and analysed at the University of Queensland Centre for Clinical Research (UQCCR). The tests that will be performed on your blood and breast milk samples are for research only and will not be used in your treatment.

UQCCR will not transfer your samples to anyone who has expressed intent to sell the samples. These samples will be stored with coded labels without your name or details or the name or details of your baby on them. Ultimately, they will be disposed of in biohazard waste bins.

You can let us know, if it is ok for us to use these samples for future, related research projects, by ticking a box below. We would only use the samples again if you tick this box and by obtaining another ethics approval.

**11 What if I withdraw from this research project?**

If you decide to withdraw from this research project, please notify a member of the research team before you withdraw.

If you do withdraw your consent during the research project, the study doctor and relevant study staff will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected by the research team up to the time you withdraw will form part of the research project results.

**12 What happens when the research project ends?**

When the project ends, you will be able to access a summary of the results if you supply an email address on the consent form.

**Part 2 How is the research project being conducted?**

**13 What will happen to information about me?**

The information about you will be coded until we have finished collecting data and then it will be non-identifiable. The data will be kept for 15 years after the information is published. We will only use this information again for future unspecified research if we obtain separate ethical approval.

By signing the consent form you consent to the study doctor and relevant research staff collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. It will be kept in a locked office, on a password protected computer. Only members of the research team will be able to access the information. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

Information about you may be obtained from your health records held at this health service for the purpose of this research. By signing the consent form you agree to the research team accessing health records if they are relevant to your participation in this research project.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified. This data will be presented as a group, not individual results.

In accordance with relevant Australian and Queensland privacy and other relevant laws, you have the right to request access to the information collected and stored by the research team about you. You also have the right to request that any information with which you disagree be corrected. Please contact the research team member named at the end of this document if you would like to access your information.

Any information obtained for the purpose of this research project and for the future research described in Section 16 that can identify you, will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

**14 Complaints and compensation**

If you suffer any adverse effect as a result of this research project, you should contact the study team as soon as possible at the contact details listed below.

**15 Who is organising and funding the research?**

This research project is being conducted by Dr Anthony Hodge. Funding for this research project is coming from internal department resources.

**16 Who has reviewed the research project?**

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of The Royal Brisbane and Women’s Hospital.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

**17 Further information and who to contact**

The person you may need to contact will depend on the nature of your query.

 **Clinical contact person**

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| --- | --- |
| Name | Dr Anthony Hodge |
| Position | Principal Investigator, available 24 hours |
| Telephone | 0412866417 |
| Email | anthony.hodge@health.qld.gov.au |

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

**Complaints contact person**

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| --- | --- |
| Name | *Dr Geoffrey Messer* |
| Position | *Quality and Safety, Anaesthesia and Perioperative Medicine* |
| Telephone | *07 3646 7154* |
| Email | *geoffrey.messer@health.qld.gov.au* |

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact the Human Research Ethics Committee of The Royal Brisbane and Women’s Hospital:

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| --- | --- |
| Reviewing HREC name | *The Royal Brisbane and Women’s Hospital* |
| Telephone | *07 3647 1007*  |
| Email | *RBWH-Ethics@health.qld.gov.au* |

**Reviewing HREC approving this research** **and HREC Executive Officer details**

**Local HREC Office contact (**MNHHS Research Governance Manager**)**

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| --- | --- |
| Position | MNHHS Research Governance Manager |
| Telephone | 07 3647 9550 |
| Email | MNHHS-RGO@health.qld.gov.au |

**18 Complaints and Compensation**

If you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

**Consent Form**

|  |  |
| --- | --- |
| **Title** | Pharmacokinetic profile and breastmilk excretion of sugammadex in pregnant women |
| **Short Title** | Sugammadex in pregnant women |
| **HREC Number** | HREC/2021/QRBW/74517 |
| **Principal Investigator** | Dr Anthony Hodge |
| **Associate Investigator** | Professor Jason RobertsAssociate Professor Victoria EleyDr Angela TognoliniDr Steven Wallis |
| **Location**  | Department of Anaesthesia and Perioperative Medicine, RBWH |

**Declaration by Participant**

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the project without affecting my future health care.

I understand that I will be given a signed copy of this document to keep.

I consent to the storage and use of blood and breastmilk samples taken from me for use, as described in the relevant section of the Participant Information Sheet, for:

• This specific research project No Yes

• Future research that is closely related to this research project No Yes

• Any future research No Yes

I would like to receive a summary of the study results by email Yes

Email address for summary of results:

|  |
| --- |
|  |
|  | Name of Participant (please print) |  |  |  |  |
|  |
|  | Signature |  |  Date |  |  |
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**Declaration by Trained Research Staff†**

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

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|  | Name of Study Doctor/Senior Researcher† (please print) |  |  |
|  |  |
|  | Signature |  |  Date |  |  |
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Note: All parties signing the consent section must date their own signature.

**Form for Withdrawal of Participation -** *Adult providing own consent*

|  |  |
| --- | --- |
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| **Protocol Number** | Version 1 |
| **Principal Investigator** | Department of Anaesthesia and Perioperative Medicine, RBWH |
| **Associate Investigator** | Professor Jason RobertsAssociate Professor Victoria EleyDr Angela TognoliniDr Steven Wallis |
| **Location**  | Dr Anthony Hodge |

**Declaration by Participant**

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with The Royal Brisbane and Women’s Hospital.

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|  |
|  | Name of Participant (please print) |  |  |  |  |
|  |
|  | Signature |  |  Date |  |  |
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Reason for withdrawal

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**Declaration by Trained Research Personnel**

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

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|  |
|  | Name of Study Doctor/Senior Researcher† (please print) |  |  |
|  |  |
|  | Signature |  |  Date |  |  |
|  |

Note: All parties signing the consent section must date their own signature.