

**IV fluids during colonoscopy**

**Participant Information Sheet/Consent Form – Person Giving Own Consent**

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| --- | --- |
| **Title** | Randomised controlled trial comparing use vs non-use of IV fluids during colonoscopy |
| **Short Title** | IV fluids during colonoscopy |
| **Protocol Number** | Version 2 |
| **Project Sponsor** | Lyell McEwin Colorectal Unit |
| **Coordinating Principal Investigator/ Principal Investigator** | Dr Elizabeth Murphy  Dr Timothy Ganguly |
| **Associate Investigator(s)**  *(if required by institution)* | Dr Ned Kinnear, Dr Gajen Perry, Dr Devinder Raju, Dr Christian, Dr Bill Wilson, Angelie Ashby RN |
| **Location** *(where CPI/PI will recruit)* | Lyell McEwin Hospital – Northern Adelaide Local Health Network |

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

The purpose of this project is to determine whether giving fluid through a drip during a colonoscopy is of any benefit to patients.

**1 Introduction**

You are being invited to take part in this research project, because you are having a colonoscopy. We are trying to establish whether giving you extra fluids through a drip during a colonoscopy makes any difference to how you feel during and after the colonoscopy.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and treatments 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 your 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 take part in the research project

• Consent to have the tests and treatments 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.

**2 What is the purpose of this research?**

Fluid is normally given through a drip during routine colonoscopies; however, there is no evidence that this makes patients feel any better. The purpose of this study is to determine whether giving fluid during colonoscopy makes patients feel better, and/or prevents a drop in blood pressure during the procedure.

We aim to compare two groups of patients; only one of which will receive fluid through a drip. We will compare how patients feel both before and after the procedure, and examine the effects of fluid on their blood pressure and routine blood chemistry tests.

This research has been initiated by the study doctors Dr Elizabeth Murphy and Dr Timothy Ganguly

**3 What does participation in this research involve?**

If you agree to participate in this trial your colonoscopy will proceed as planned; the only difference being that you will be placed in one of 2 equally sized groups. You will have a 50% chance of receiving or not receiving intravenous fluid during the procedure. You may not be aware of whether or not you received fluids.

If you agree to participate in this study the following will occur in addition to all of the regular components of a colonoscopy:

* Surveys will be conducted before and after the procedure that will assess your thirst/dehydration/general well being
* A follow up survey will be conducted approx. 24 hours post the procedure via telephone call
* An initial sample of blood will be sent for basic biochemical analysis prior to the procedure (this will not require any additional needles)
* A second sample of blood will be collected after the procedure (this will require a separate needle)
* If your blood pressure drops significantly you will receive medication to increase it
* All of the data collected will be kept in a database for the duration of the study, names and D.O.B will not be recorded

You will be participating in a randomised controlled research project. Sometimes we do not know which treatment is best for treating a condition. To find out we need to compare different treatments. We will put people into 2 groups and give each group a different treatment. The results are compared to see if one is better. To try to make sure the groups are the same, each participant is put into a group by chance (random).

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 medication, tests and medical care required as part of the research project will be provided to you free of charge.

If you decide to participate in this research project, the study doctor will inform your local doctor.

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

You will not be required to do anything different yourself if you participate in this study, with the exception of answering a phone questionnaire 24 hours following the study.

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

400 people will be participating in this study, 200 in each group. The study is only being conducted at the Lyell McEwin Hospital.

**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.

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 Lyell McEwin Hospital.

Your position in the waiting list for your colonoscopy will not be effected if you elect no to participate, or if you withdraw part way through the study.

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

There will be no clear benefit to you from your participation in this research.

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

Having a bowel preparation for a colonoscopy can sometimes have side effects; such as nausea and dehydration. Administering fluid during a colonoscopy has not been shown to reduce these side effects; however, this has not been studied in detail before. This study hopes to show whether there is any benefit from fluid. There is a small chance if you are in the group receiving no fluid you may experience more side effects. This is one of the things we hope to find out from the study.

One potential disadvantage from participating in this study is that you will require one additional blood test, which will be taken in recovery after the procedure. You will also be required to participate in questionnaire both in person on the day of the colonoscopy and by telephone the day following.

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.

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

If you participate in this study 2 blood chemistry tests will be taken, these samples will be stored like normal blood tests for a short period of time. The results will be recorded in the study, but will also be available in your hospital records.

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

If you decide to withdraw from the project please notify your treating doctor or nurse, it will have no impact on how you are treated during and after your procedure.

**11 Could this research project be stopped unexpectedly?**

This research project may be stopped unexpectedly for a variety of reasons. These may include reasons such as:

• Unacceptable side effects

• If the patients in the group receiving no fluid are shown to have more side effects when the results are being analysed during the study

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

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

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. You will be assigned a code if you are involved in the study, and your information will only be identifiable by this code. 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.

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, except with your permission.

Information about your participation in this research project may be recorded in your health records.

In accordance with relevant Australian and South Australian privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please contact the study 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 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.

**13 Complaints**

If you have any complaints about your treatment during the study please contact one of the study coordinator or the consumer advisor at the Lyell McEwin Hospital.

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

This research project is being conducted and funded by the Colorectal Surgical Unit, Gastroenterology Unit and Anaesthetic Department at the Lyell McEwin Hospital.

**15 Injury and Compensation**

No significant injuries are expected to occur during this study.

**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 Lyell McEwin Hospital/Queen Elizabeth Hospital/ Royal Adelaide 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.

If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact the principal study doctor on 08 8182 9309, Dr Murphy’s secretary.

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 | Christine Beal |
| Telephone | 08 8182 9658 |
| Email | Christine.beal@health.sa.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:

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| --- | --- |
| Reviewing HREC name | RAH/TQEH/LMH HREC |
| HREC Executive Officer | Heather O’Dea |
| Telephone | 08 8222 4139 |
| Email | Heather.o’dea@health.sa.gov.au |

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

**Local HREC Office contact (Single Site -Research Governance Officer)**

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| --- | --- |
| Name | Allison Barr |
| Position | Clinical Governance Officer - LMH |
| Telephone | 08 8182 9346 |
| Email | Allison.barr@health.sa.gov.au |

**Consent Form -** *Adult giving own consent*

|  |  |
| --- | --- |
| **Title** | Randomised controlled trial comparing use vs non-use of IV fluids during colonoscopy |
| **Short Title** | IV fluids during colonoscopy |
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| **Associate Investigator(s)**  *(if required by institution)* | Dr Ned Kinnear, Dr Gajen Perry, Dr Devinder Raju, Dr Christian, Dr Bill Wilson, Angelie Ashby RN |
| **Location** *(where CPI/PI will recruit)* | Lyell McEwin Hospital – Northern Adelaide Local Health Network |

**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 give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to Lyell McEwin Hospital concerning my disease and treatment for the purposes of this project. I understand that such information will remain confidential.

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 study without affecting my future health care. I understand that I will be given a signed copy of this document to keep.

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|  | Name of Participant (please print) | |  |  |  |  |
|  | | | | | | |
|  | Signature |  | | Date |  |  |
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**Declaration by Study Doctor/Senior Researcher†**

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 |  |  |
|  | | | | | | |

† A senior member of the research team must provide the explanation of, and information concerning, the research project.

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

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

|  |  |
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| **Project Sponsor** | Lyell McEwin Colorectal Unit |
| **Coordinating Principal Investigator/ Principal Investigator** | Dr Elizabeth Murphy  Dr Timothy Ganguly |
| **Associate Investigator(s)**  *(if required by institution)* | Dr Ned Kinnear, Dr Gajen Perry, Dr Devinder Raju, Dr Christian, Dr Bill Wilson, Angelie Ashby RN |
| **Location** *(where CPI/PI will recruit)* | Lyell McEwin Hospital – Northern Adelaide Local Health Network |

**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 Lyell McEwin 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 Study Doctor/Senior Researcher†**

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 |  |  |
|  | | | | | | |

† A senior member of the research team must provide the explanation of and information concerning withdrawal from the research project.