ST JOHN OF GOD
Midland Public & Private Hospitals

Expired Nitrous Oxide predicting ReADmission (NORAD) Study

Patient Information Sheet

Researchers in the St John of God Midland Hospital are looking for volunteers with known chronic obstructive lung disease (COPD - a smoking related disease of the lungs) who have been admitted to hospital for a flare up of the disease. The study is testing a new device that measures the intensity of inflammation in the lung airways. This may help guide treatment options in the future.

You have been admitted with a diagnosis of acute exacerbation of known or suspected COPD and you may be suitable to volunteer as a participant in this study.

What is the purpose of the study?

COPD is a common disease and patients with moderate to severe COPD often will require an admission to hospital during an exacerbation (flare-up). Some patients with COPD who have already had one admission to hospital are at high risk of more hospital admissions in the next 12 months. Every admission to hospital carries a risk of further loss of lung health and other health problems. Avoiding or reducing more hospital admissions is therefore important. To do this we first need to learn which patients are at high risk of ending up in hospital again. If we can pick who is most at risk then hopefully we can treat these people differently and avoid more admissions.

The objective of this study is to assess whether a new device (NIOX) that measures the amount of Nitric Oxide (NO) in a patient's breath can help identify patients at high risk of hospital re-admission. The NIOX device measures very tiny amounts of the gas "NO" present in the air someone breathes out. This tells the researches how much inflammation is present in the lung. Finding out how much inflammation is in a patient's lungs may help pinpoint which patients are at higher risk of ending up back in hospital.

What will it involve?

You will be asked a few questions to see if you are suitable to participate in the study. And if you agree to participate you will undergo some simple bedside tests.

1. On the **first day** of the study (while you are in hospital):
   - Fill in a patient questionnaire. This will take approximately 10 to 15 minutes.
   - Perform two breathing tests in you room:
     - The first test will be the *NIOX test* – a simple breathing test were you will need to take a deep breath and then blow out steadily for a few seconds like a breathalyser test
     - The second test is called *spirometry test* - it is a simple breathing test to assess the health of your lungs. You need to fill your lungs with air and then breathe out as fast and for as long as you can. This test will need to be repeated at least 3 times.
   - Have a blood test. As you will have already had blood tests when you were initially admitted to hospital an extra blood test will often not be needed.

2. At **six weeks** at your clinic follow-up appointment after your discharge from hospital:
   - A short questionnaire
   - Repeat NIOX and spirometry breathing test

   This 6 week appointment is part of usual care after a patient has been in hospital but the appointment may be slightly longer (approximately 30 minutes) because of the extra NIOX test.
3. **Phone calls at 3, 6, 9 and 12 months after your hospital admission**:

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- A further questionnaire via *phone contact only* will be performed at 3, 6, 9 & 12 months.
- If you cannot be contacted by phone, the researchers will contact your nominated next-of-kin and/or general practitioner. Your general practitioner will be informed of study participation.
- After 12 months, the study researchers will contact your nominated general practitioner for any hospital discharge summaries to see if you were admitted to hospital, what the main problem or diagnosis is/was and when you were admitted.

Do I have to participate?

Absolutely not! Participation is voluntary and if you prefer not to participate, it will not affect your medical care at St John of God Hospital Midland.

Are there any risks to me by participating in this study?

All effort is taken to minimise any risks.

- This study does not involve any treatment intervention (no treatment procedures or trial medications). All additional tests, except the NIOX test, are considered part of usual care.
- The additional NIOX tests can be a little tricky to perform especially when you are unwell, but it is very safe.
- Any personal information that is recorded about you will be de-identified and kept secure.

What are the benefits to participating in this study?

There will be no direct benefits to you. You will be receiving best standard care through your doctors and other health staff.

What are the costs to me?

We are not able to reimburse you for your time or any extra expenses that you may occur when participating. However, no significant additional costs to you are anticipated.

Who has reviewed this study?

The St John of God Healthcare Human Research Ethics Committee has reviewed this study and has given approval for the conduct of this study. This research conforms to the principles set out by the National Statement on Ethical Conduct in Human Research and abides by the Good Clinical Practice Guidelines.

How can I get more information?

If you have any questions, please contact:

Midland Physician Service: Phone no. 08 9462 5300 or MPS.admin@sjog.org.au
Dr Francesco Piccolo or Dr David Manners: Phone no. 08 9462 4000

Yours sincerely

Dr Francesco Piccolo
Respiratory Specialist and Researcher
Head of Service, Respiratory & Sleep

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Patient Consent Form

Researchers: **Dr Francesco Piccolo and Dr David Manners, St John of God Midland Hospital**

Participant Name: _____

Date of Birth: _____

NOTE: If you are still unclear about anything you have read in the Participant Information Sheet and Consent Form, please speak to your doctor before signing this Consent.

1. I have been given information, both verbally and in writing, about this study and having had time to consider it, am now able to make an informed decision to participate.
2. I have been told about the potential benefits and known risks of taking part in this study and I understand what this means to me.
3. I understand that my nominated General Practitioner (GP) will be informed of my participation in the study and may be contacted during the study period of 12 months obtain information about my respiratory health.
4. I provide permission for the study researchers to access any discharge summaries relating to subsequent hospital admissions for the 12 months after participation from my nominated GP.
5. I have been given the opportunity to have a member of my family or a friend with me when this study was being explained to me. I have been able to ask questions and have had all my questions answered.
6. I know that I do not have to take part in this study, and that my decision to take part is voluntary. I understand that I can withdraw from this study at any time without affecting my medical care.
7. I understand that participating in this study does not affect any right to compensation, which I may have under statute or common law.
8. I accept that by taking part in this research, that any information obtained about me during the study may be published, provided that my name **and** other identifying information **are** not used.

Name of Participant	Signature of Participant	Date

Name of Researcher	Signature of Researcher	Date

The St John of God Healthcare Human Research Ethics Committee has granted approval for the conduct of this study. If you have any concerns about the ethics or code of practice of the study, please contact the Executive Officer of the St John of God Human Research Ethics Committee on (08) 9382 6940 or ethics@sjog.org.au .

Study participants are to receive a copy of the Participant Information Sheet and Consent Form for their personal record.

PIS and Consent Version 1, March 2018