



# Moxidectin

## What could make moxidectin a better scabies treatment?



*This flipchart has been put together to help you decide if you would like to take part in our research project.*

Dr Dev Tilakaratne is the study doctor from the Royal Darwin Hospital. He is an expert in skin problems and thinks that this study is important for the future treatment of scabies.

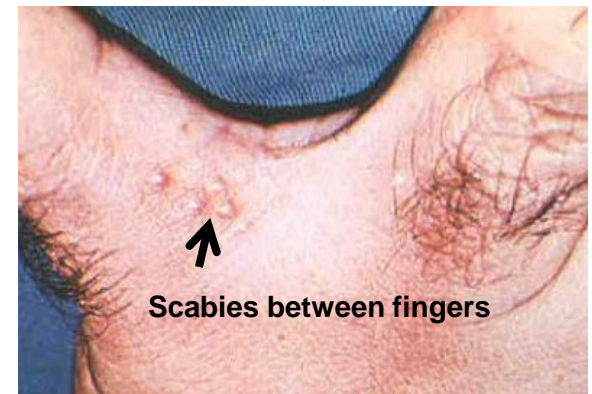
# New Medicine – Moxidectin

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This is a story about scabies and a new medicine called **Moxidectin** that we think will kill scabies mites and hatching mites from eggs laid in the burrow under the skin.



When a person first gets scabies, he or she has an itchy rash in a few places on the body like near the arm pits and between the fingers.



# How do people get scabies?

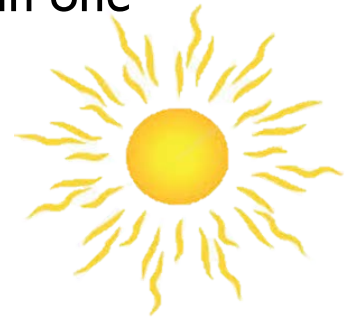
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Scabies mites can move from one person to another after contact for a long time when not treated with medicine.



People can also get scabies from sharing clothes, sheets, blankets and mattresses with someone who has scabies. Sometimes all the people living in one house can be infected.

We know scabies mites die in dry or hot places but when on people we need medicine to kill them.



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# What do scabies look like?



Dr Dev is using a machine called 'reflectance confocal microscope (RCM)', so he can see what the scabies mite and egg looks like and what they do while living under someone's skin





# Current treatments for scabies?

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5% permethrin (Lyclear) cream is effective but must be applied correctly and at least twice to kill newly hatching mites



Ivermectin is effective but requires 2 doses at least 7 to 14 days apart to kill newly hatching mites

These 2 medicines have been used for a very long time but unless used correctly may not kill all the scabies mites. We think there is a need for a new scabies medicine that is more effective and easier to use, we think that this is Moxidectin.

# What is moxidectin?

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Moxidectin was originally developed as a medication for animals to kill parasites much like ivermectin.

Moxidectin is licenced for use in humans with onchocerciasis – a tropical disease caused by a parasitic worm that can migrate into the eye and cause blindness, this is common in Africa.

This study is about giving moxidectin to people with scabies and seeing how long it will take to kill the scabies mites.

Moxidectin is a small almond shaped white tablet and is taken by mouth.



# *What might make Moxidectin a better scabies treatment?*

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## **What we know from other studies around the world is that:**

- Moxidectin when given to animals with scabies killed the scabies mites.
- Moxidectin remains in our bodies for a lot longer than Ivermectin

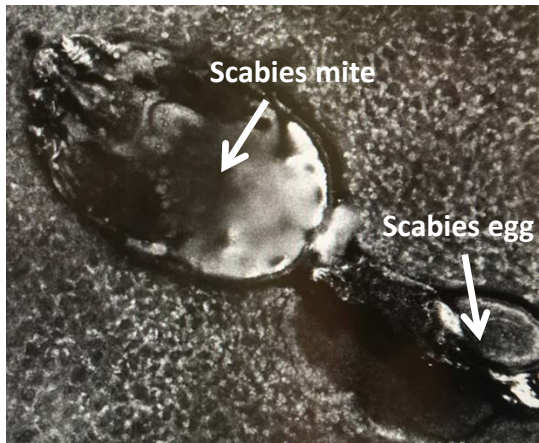
## **What we think but have to prove:**

Because Moxidectin stays in our bodies a lot longer than Ivermectin we think that one treatment dose will kill the scabies mite and remain in our bodies long enough to also kill the newly hatching eggs.

This study is wanting to find out what is the right amount (or dose) of Moxidectin medicine needed to kill scabies mites and their newly hatching eggs in adults humans?

# How is moxidectin different to ivermectin?

Medications	Ivermectin <i>(current treatment)</i>	Moxidectin <i>(new treatment)</i>
Time taken for levels to peak in the blood	Approx. 4 hours	Approx. 4 hours
Time taken for half of the medicine to be eliminated or destroyed in the body. This is called the ' <b>half life</b> '.	12 hours	20 to 47 days
Number of treatments required to kill the scabies mite and hatching eggs	Two treatments (7 to 14 days apart)	Once only



## Why is the 'half life' important.

- Both medications only kill the scabies mite not the egg that mites will hatch from.
- The half life of Moxidectin is a lot longer which means when the scabies egg hatches there is still enough moxidectin in the body to kill the newly hatching mites



# What's the right amount of Moxidectin?

Currently there are 3 different amounts of Moxidectin that we will be using, the 3 amounts are 2mg, 8mg and 20mg. However a committee will review all the available information to see if the doses are working. They may decide to change nothing, remove one of the current doses or add a 36mg dose. Up to approximately 36 people will participate in this study with 6 people assigned to each group.



**2 mg of Moxidectin**



**6 people**

**8 mg of Moxidectin**



**6 people**

**20 mg of Moxidectin**



**6 people**

**36 mg of Moxidectin**



**6 people**

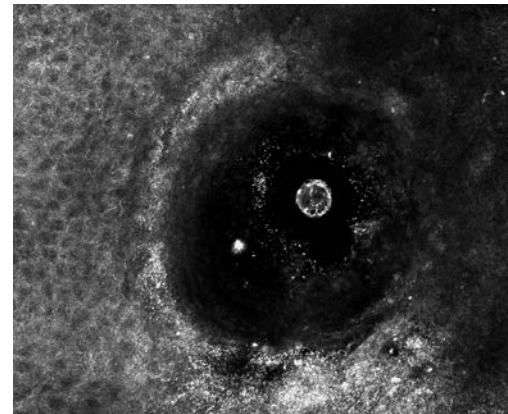
# How will we know what the right amount of Moxidectin?

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We will be looking at the levels of moxidectin in the blood of the people who join the study and we will be observing the scabies mite to see when they die. We will then compare the results to see which amount of moxidectin works the best to kill the scabies mite. This will tell us the right dose.



Alive scabies mite



Dead scabies mite

# Who can join?

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You need to be 18 years and older

Have a current scabies infection that you have not taken any medication or lotions for

Plan to stay in Darwin for the next month

Not using any creams or lotions

Be reasonable healthy

Be willing to attend 9 to 10 study visits over 13 weeks with one of these visits requiring you to be observed for 8-9 hours, all other visits will take approximately 1-2 hours

Not planning to have children within the next 6 months (both male and female)

Happy to take tablets

Willing for a medical doctor to do a full physical examination (body check).

Willing to have your blood taken on a number of occasions

Willing for your skin to be checked regularly

# *Do I have to take part?*

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No you don't. If you say no, that is ok. It is up to you.



If you say yes, and then change your mind later on, that is okay. All you need to do is tell the researcher that you don't want to take part anymore. You also don't need to answer any questions that you don't want to.



# What do I have to do if I say Yes?

The study doctor will need to perform a few **screening** tests to make sure you are eligible



Check that you have scabies with a dermoscope



Ask you if you are taking any medicine or have any health problems



Full body examination by a study doctor (your choice of male or female), height, weight, temperature, heart rate, breathing rate and take your blood pressure



Take some blood to send for tests to make sure that your liver, kidney's, red and white blood cells are ok. Over the whole study this will be 125mls (half a cup).

You also need to be able to attend clinic for 3 days after you have the Moxidectin, then 1 week, 2 weeks, 1 month and 3 months later. If your screening tests are ok and you are happy to attend the clinic we will let you know and book a time and day for you to start the study



# Consent



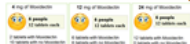
## MOXIDECTIN (MDGH-Mox-2001)

### Participant Consent Form

**THIS MEANS YOU CAN SAY NO**

**Site:** Royal Darwin Hospital  
**Study Sponsor:** Medicines Development for Global Health  
**Site Researcher:** Dr Dev Tilakaratne **Telephone:** 08 8922 8888  
**Full Project Title:** A Phase II, randomized, double-blind, parallel group dose finding study of single oral doses of moxidectin in adults with scabies

- I understand the information given to me about this study and I am 18 years or older
- I understand I will receive 10 tablets but will not know how much, if any moxidectin I was given.



- I understand the purposes, procedures and risks of the research described in the project.
- I give permission for my doctors, general practitioner or health care clinic to release information to the research team concerning my disease and treatment for the purposes of this project. I understand that such information will remain confidential.
- I give permission for a member of the research team to phone me, my GP or health clinic within the first 90 days following enrolment onto the study for information on my current health.
- I have had the opportunity to ask questions and I am satisfied with the answers I have received.
- I understand that if I withdraw from the study, the information already collected will be retained and used to protect the integrity of the study, with my personal information removed.
- I understand that I can withdraw at any time during the study without affecting my current and future health care.
- By signing this consent form I agree to participate in the Moxidectin (MDGH-MOX-2001) study, as described in the participant information sheet, version 1.0.

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

Name of Participant (please print) \_\_\_\_\_  
 Signature \_\_\_\_\_ Date \_\_\_\_ / \_\_\_\_ /20\_\_

#### Declaration by 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.

Name of Researcher (please print) \_\_\_\_\_  
 Signature of Researcher \_\_\_\_\_ Date \_\_\_\_ / \_\_\_\_ /20\_\_

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

Only complete below if an interpreter was used or a witness to the signature is required

Name of Interpreter (please print) \_\_\_\_\_  
 Signature \_\_\_\_\_ Date \_\_\_\_ / \_\_\_\_ /20\_\_

If you agree to be a part of this study you will need to sign a consent form.



# What's next when I come to clinic?

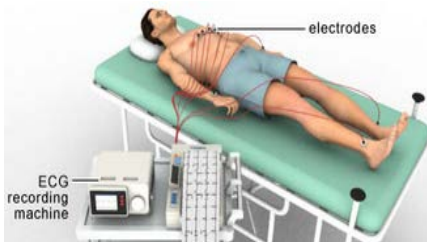


**No eating or drinking** except for water:

- ❖ From midnight prior to coming to the clinic on the day you are going to be given the Moxidectin.
- ❖ 2 hours after you have taken the treatment
- ❖ You need to fast because some foods change the amount of Moxidectin that is absorbed into the body



Perform a less invasive body assessment (study doctor), height, weight, temperature, heart rate, breathing rate and take your blood pressure



You will also have an ECG (machine that reads your heart) to make sure your heart is healthy.



# If all this is ok



Dr Dev will check your body for scabies mites using the new machine called reflectance confocal microscope (RCM). Dr Dev will mark 2 locations with scabies mites

These 2 locations will be checked a number of times and photos similar to this picture will be taken by Dr Dev to see when the mite dies, and what happens to the hatching eggs.



We also need to check your blood 5 times on the first day when you take the medication for how much Moxidectin is in your blood. This is about a total of 30mls or 6 teaspoons. We will ask your permission to insert an IV cannula to take blood from on the day you receive Moxidectin so that we do not have to use a needle each time.

The IV cannula will be removed after 8 hours.



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# Receiving the Moxidectin?



▶ You will receive either 2mg, 8mg, 20mg or maybe 36mg of Moxidectin:

**2 mg of Moxidectin**



**6 people  
10 tablets each**

1 tablet with Moxidectin  
9 tablets with no Moxidectin

**8 mg of Moxidectin**



**6 people  
10 tablets each**

4 tablets with Moxidectin  
6 tablets with no Moxidectin

**20 mg of Moxidectin**



**6 people  
10 tablets each**

10 tablets with Moxidectin  
0 tablets with no Moxidectin

- ▶ No-one including you will know how much Moxidectin you receive, each person receives the same number of tablets to swallow (1 after the other).
- ▶ The tablets with no Moxidectin will look the same but they **do not** have Moxidectin
- ▶ Only the person who makes up the medication boxes knows which boxes have 2, 8, 20 or maybe 36 mg of Moxidectin.

If the committee add an additional dose then the number of tablets will change to 18 as below

**2 mg of Moxidectin**

**6 people  
18 tablets each**

1 tablet with Moxidectin  
17 tablets with no Moxidectin

**8 mg of Moxidectin**

**6 people  
18 tablets each**

4 tablet with Moxidectin  
14 tablets with no Moxidectin

**20 mg of Moxidectin**

**6 people  
18 tablets each**

10 tablet with Moxidectin  
8 tablets with no Moxidectin

**36 mg of Moxidectin**

**6 people  
18 tablets each**

18 tablet with Moxidectin  
0 tablets with no Moxidectin

# Timeline of study procedures

DAY	-7 to -1	Day 0 (initial 8hrs)						Day 1	Day 2	Day 3	Day 7	Day 14	Day 28	3 Month
Hours	Screen	Baseline pre-treatment	0 hrs	2hrs	3hrs	4hrs	8hrs	24hrs	48hrs	72hrs	1wk	2wk	4wks	12wks
Written informed consent	✓													
Rx =Treatment			*Rx											
Fasting		8 hours prior to Rx	2 hour post Rx											
Medical History	✓													
Medication assessment	✓													
ECG	✓													
Vital signs	✓	✓					✓	✓		✓	✓	✓	✓	✓
Cannula		✓												
PK blood sample Plasma Storage		✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Hematology & serum chemistry	✓	✓									✓		✓	
Pregnancy test	✓ serum	✓ urine											✓ urine	✓ urine
Height	✓													
Weight		✓												✓
Assessment of clinical signs of scabies infection		✓												
Dermoscope		✓								✓				
RCM (post PK sampling)	✓	✓				✓	✓	✓	✓	✓	✓	✓	✓	
Body (physical) assessment	✓ Complete	✓ Modified						✓ Modified		✓ Modified	✓ Modified	✓ Modified	✓ Modified	✓ Modified
Patient reported outcome		✓												
Safety assessment			✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓





# *Some other things that you will have to do*

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## **Medicines:**

- ▶ You must tell study staff about all the medications you are taking this includes any bush medicines.
- ▶ No other treatment for scabies can be used over the one month you are on the study.
- ▶ No medication creams can be used.
- ▶ Ask the doctor before you take any allergy medications.

## **The 2 scabies mites that Dr Dev identified:**

- ▶ Please try to avoid scratching the areas with these scabies mites (the Dr will show you these areas).

# Some side effects from Moxidectin:



- ▶ Moxidectin is a new medicine and therefore not all side effects are known. Moxidectin has been given to 254 healthy volunteers at doses between 3mg and 36mg. The most common side effects were headache, rhinitis (stuffy nose), flu like symptoms, an upset stomach (feeling sick or runny poos) or dizziness. Most side effects were mild.
- ▶ For 1105 patients treated with moxidectin for a parasitic worm infection called 'onchoceriasis' the side effects were due to allergic reactions caused by the worms dying in the skin and eyes as a result of treatment. The most common side effects were itching and rash, swelling, headache, blood pressure and heart rate changes, body pain, fever and chills, an upset stomach, and changes in the number of some immune cells in the blood. In most cases, these were mild, went away on their own and lasted less than a week.

# Further information

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- ▶ We will be monitoring the safety of moxidectin in adults with scabies, this is why we will be asking you questions about how you are feeling and why the doctors will do regular physical exams when you come in for study visits.
- ▶ There is also a risk associated with blood draws such as mild discomfort and or localised bruising at the site.
- ▶ Please let us know if you are worried about anything. Often scabies treatment can cause the itchiness to worsen over a couple of weeks. This is true for 5% Permethrin (lyclear) and Ivermectin.
- ▶ Prior to any face to face study visits the study team will contact you to confirm if you are if you are experiencing symptoms that suggest a COVID-19 infection, or if you know you have been in contact with someone with COVID-19. You may be required to follow site-specific instructions to manage the risk of COVID-19 spread, including wearing a mask and maintaining an appropriate level of social distance from other patients and clinic staff.

# *Some good things that can happen in the project*



- ▶ You will have a health check-up including a basic physical examination, vital signs measurements and blood tests to determine your current state of health. The results of the tests will be shared with your General Practitioner.
- ▶ There is a possibility that this experimental treatment gets rid of the mites after a single dose taken by mouth. However, this is not guaranteed. So you will be closely followed by a study doctor. If the mites remain then you will be given alternative treatments.
- ▶ Treatment with 5% Permethrin (Lyclear) cream will be offered to the members of your household and other close contacts at no cost. Treatment of your close contacts will help to make sure you are not infected again.
- ▶ If Moxidectin works for treatment of scabies in this study, the study Sponsor will conduct much larger studies with the dosage (mg) that worked the best. The aim of the future studies will be to have moxidectin registered with the US Food and Drug Administration (FDA) and other regulatory authorities as the first line of defense in the treatment of scabies.

# What happens to my blood samples?



- ▶ Some of the blood sample that we collect will go to the local pathology department to check your general health.
- ▶ The remainder of your blood samples will be used to check the level of Moxidectin in your blood and some plasma will be used in the development of scabies testing.
- The test required to determine the level of moxidectin can only be performed by an accredited laboratory. There is no laboratory in Australia that can perform this test so we need to send your blood sample overseas. These will be sent when we have finished recruiting for the study and will take a few days to arrive.
- A sample of your plasma will also be used in future ethically approved research to help develop a test that will improve diagnosis of scabies. Examples of a test include looking for specific markers of an immune response (antibodies) produced in the body during a scabies infection. None of your personal information will be used.
- All blood samples will be destroyed after 2 years by burning and no samples will be used for genetic testing.



# What happens to the information about me?



- ▶ Any information about you which we obtain for this research project will remain confidential and will only be used for the purpose of this research project. Your data excluding your name and personal details will be shared with the study Sponsor, regulatory authorities and for the purpose of publication for dissemination of results. Your data will only be identified by a unique subject number. The results will be written so that no one will know who was in the project. All information about you will be kept safe in a locked filing cabinet in a secure building and on a special computer with a password.
- ▶ The Sponsor and regulatory authorities require access to your original medical records to ensure that the study has been conducted correctly and that the data is accurate. By signing the Participant Consent Form you are authorizing access.
- ▶ A requirement of the study is to keep your data for at least 15 years. In accordance with country and/or Territory laws, you have the right to access the information collected and stored by the researchers about you. Please ask the study staff if you wish to do so.
- ▶ A description of this clinical trial may be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time



# Cost and compensation

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- ▶ There are no cost to you for taking part in this research study. All medication, tests and medical care that are part of the research study will be provided to you free of charge. The Sponsor, Medicines Development for Global Health, will pay for this.
- ▶ If you are eligible and complete the study you will be compensated for your time. You will also be reimbursed costs reasonable for any travel, parking, meals and other expenses.
- ▶ If your screening results show that you are not eligible for the study or you withdraw prior to taking the study tablets, you will receive no compensation. If you wish to withdraw from the study before completion, or if the study doctor decides that it is in your best interests to withdraw from the study, the amount of the payment will be adjusted based on how long you took part and which visits you completed.
- ▶ The Sponsor follows the Medicines Australia guidelines for compensation for an injury occurring in a clinical trial. If an injury results from your participation in the study even though the study medication is administered according to the approved protocol, you will be covered by the Sponsor's insurance.

# *Anything else?*

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You need to understand why we are doing this project, and what we will be asking you to do in this project. Talk about the project with your family or friends and ask questions about the project before making a decision.

This study is sponsored by a not-for profit organisation called Medicines Development for Global Health.

*Thank you for reading this*

# *For more information*

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To find out more or if you have any concerns about your participation, please contact any of the following team members:

Dr Dev Tilakaratne

Email: [Dev.Tilakaratne@nt.gov.au](mailto:Dev.Tilakaratne@nt.gov.au)

Tel: 89 22 8888

Study Team: [moxi@menzies.edu.au](mailto:moxi@menzies.edu.au)

Tel: 89 46 8522

Study Sponsor: Medicines Development for Global Health

[www.medicinesdevelopment.com](http://www.medicinesdevelopment.com)


If you have any concerns or complaints, please let the ethics committee know on:


Email: [ethics@menzies.edu.au](mailto:ethics@menzies.edu.au)

Tel: (08) 89 46 8600

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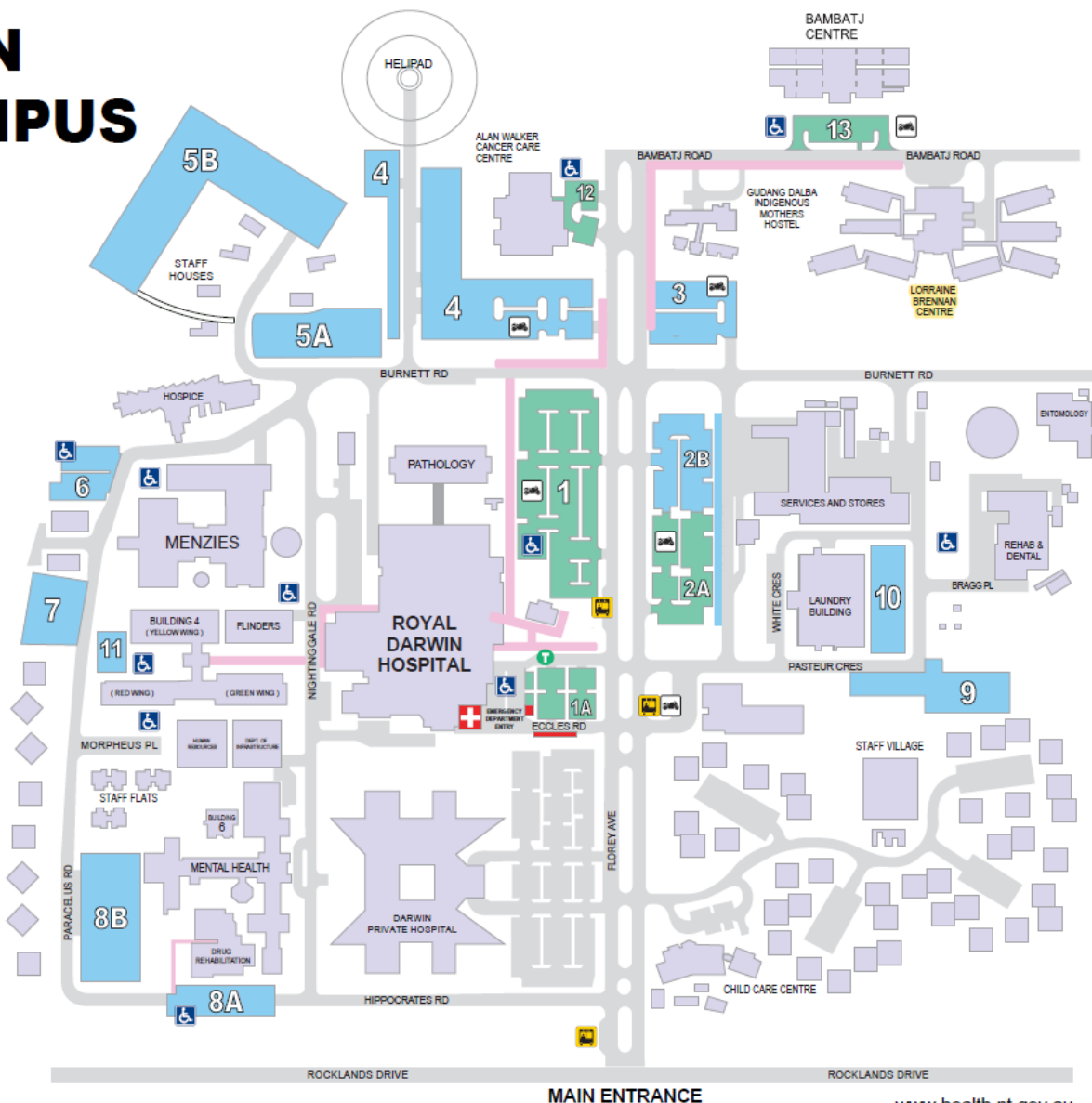
 Motorcycles

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Penalties will apply for non-compliance in accordance with by-laws.

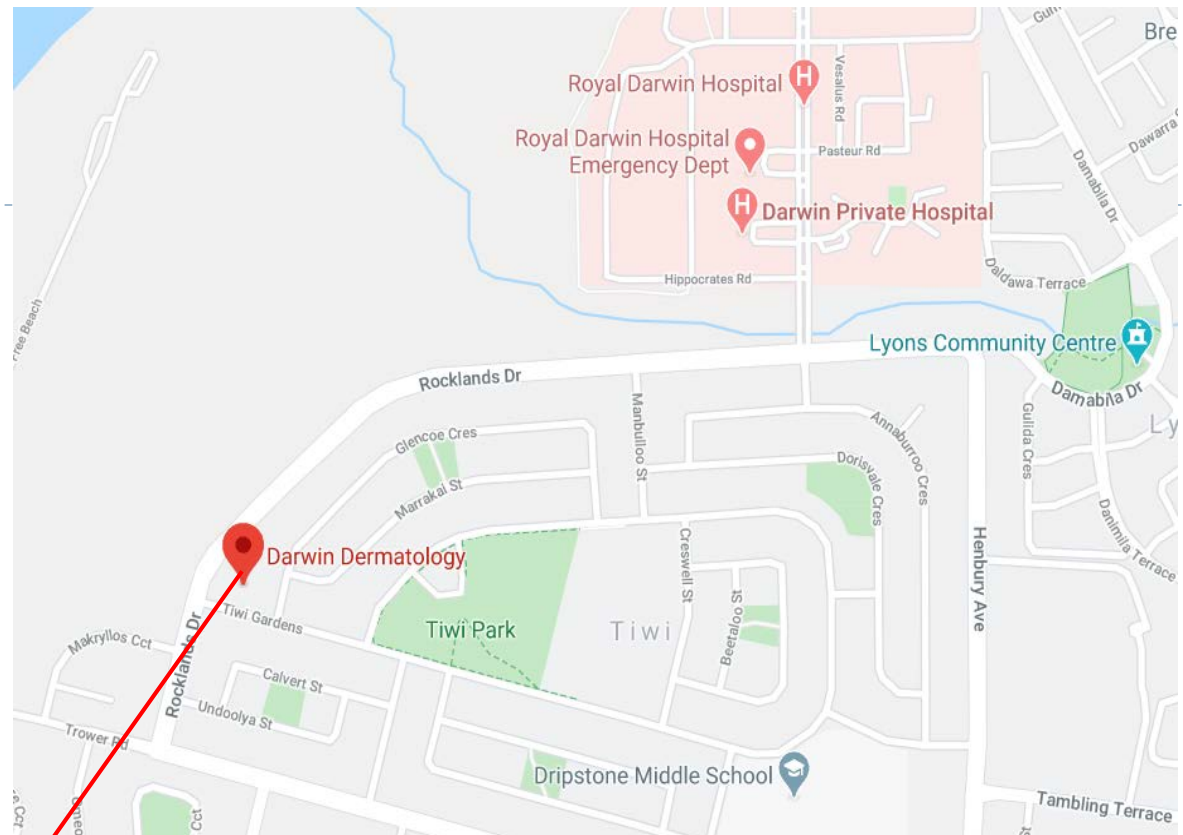


MAIN ENTRANCE

[www.health.nt.gov.au](http://www.health.nt.gov.au)



For additional precautions due to COVID 19 measures participants visits will now be located at the Darwin Dermatology clinic instead of Royal Darwin Hospital



# Message for women only

(NOTE: this page will be separated from the flipchart)

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If a woman is pregnant or breastfeeding she will not be able to go on this study. We do not know the effects of Moxidectin and if it is safe for the unborn child or newborn child through breastmilk. You will be asked if you are currently using effective contraception by the study doctor.

All women of childbearing age who want to go on this study will have their blood and urine tested to find out whether they are pregnant or not.

You should not become pregnant for at least 6 months after you receive the study medication, if you do please let the study doctor know immediately.

# Message for men only

(NOTE: this page will be separated from the flipchart)

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- ▶ If you are male, you should not father a child or donate sperm for at least 6 months after you receive the study medication.
- ▶ If you are a male participant, you should advise your study doctor if you father a child for at least 6 months after you receive the study medication. Your study doctor will advise on medical attention for your partner should this be necessary. You will be asked if you are currently using effective contraception by the study doctor.