



The science of integrative medicine

Name of company sponsoring the study:	Max Biocare
Name of chief investigators:	Professor Caroline Smith, Professor Alan Bensoussan, Dr Jennifer Hunter, Professor William Ledger, and Dr Andrew Davidson
Name of other investigators:	Dr Carolyn Ee, Mr Paul Fahey, and Afshan Khan
Address of research site:	National Institute of Complementary Medicine Building 5, Campbelltown Campus Western Sydney University
Phone number:	02 4620 3777 Out of hours/emergency contact: 0414 357 363

## Participant Information Sheet

**Project Title:** *A clinical trial of the efficacy and safety of Hominax to improve sperm health*

**Protocol ID Summary:** *Max Biocare002*

You are invited to participate in a research study being conducted by Professor Caroline Smith from the National Institute of Complementary Medicine at Western Sydney University (NICM Western Sydney University). You are being asked to take part in this research study because you have been identified as someone who may benefit from a potential new treatment for sperm health

### What is the purpose of this study?

You are being asked to participate in a research study of a new vitamin supplement called Hominax.

This is a clinical research study designed to evaluate the safety and effectiveness of Hominax capsules (given by mouth) compared to placebo (a tablet that does not contain any medicine) for improving sperm health. Researchers use a placebo to see if the study treatment works better or is safer than not taking anything. At the moment, Hominax is considered an experimental supplement as it is unknown if it has an effect on sperm health. However, it is thought that Hominax may decrease damage to sperm and improve sperm production and quality.

When sperm are produced in low numbers, are abnormally shaped, or are not able to move well, this may reduce the ability of sperm to penetrate and fertilise an egg.

This study will measure the number, shape and ability of your sperm to move well to determine the effect of the study treatment.

Hominax contains ingredients that are all approved for human consumption and use in complementary medicines by the Australian Therapeutic Goods Administration (TGA, and is listed on the Australian Register of Therapeutic Goods for sale in Australia.

### **Will the study treatment be available after the end of study?**

All completing participants who were being treated with placebo during the study will be provided with the opportunity to take Hominax free of charge for 6 months if the product is found to be effective on completion of the trial. However, if you take Hominax during the study you will not be provided with Hominax free of charge after the end of the study, that is, after all participants have completed the study and follow-up. The study doctor will only know what you have been taking after all participants have completed the study. Study treatment will be provided approximately six months after the conclusion of the last subject visit.

### **How many other people will be in the study?**

There will be approximately 122 people enrolled in this study. The study is being done at several different research sites in Australia. Approximately 20 people will be enrolled at this site.

### **How long will participation in this study last?**

You will be in this study for approximately 26 weeks. There are six study visits in total. Four of these visits (Screening, Week 0 (Start of Study), Week 16 and Week 24) involve visiting the clinic. The other two visits (Week 2, Week 26) are telephone contact visits. Site staff will call you and obtain some information over the telephone.

### **What will happen before the research study begins?**

If the study is of interest, you can proceed to initial self-screening by answering some questions on the on-line survey. If you appear to meet the initial eligibility criteria you will be automatically directed to a research officer for a short phone conversation to confirm that the trial is right for you. Your formal consent will be sought before we do any study related activities.

### **What will happen during the research study?**

Following phone screening you will be invited to attend a meeting **with the research officer for more detailed screening which will take about 45 minutes**. The purpose of the screening visit is to find out if you meet all of the requirements to take part in this research study. You can elect to come to our Campbelltown campus for the visit, or you can have this visit done over the telephone.

During the screening visit, you will be asked to have the following tests and procedures:

- Your written Informed Consent will be obtained.
- We will check you satisfy the study inclusion/exclusion criteria.

By the end of the screening visit, the study doctor will determine if you are eligible to continue into the study. If you will not be able to continue in the study, the study doctor will explain why and will discuss with you other treatment options. If you have not had a HIV/Hepatitis B and C test in the previous six

months, this is required for safety regulations. If you test positive for HIV, Hepatitis B or C you will not be eligible to enroll and your doctor will discuss further management with you.

You will then be required to provide a fresh semen sample by masturbation for analysis at a specialised fertility clinic. At present we have clinics located in Liverpool, Miranda and Randwick.

- You will also be asked to have a blood test. A blood sample (10 mls) will be obtained for safety checks (your blood count, liver function and kidney function) and vitamin and mineral levels. You will attend for the blood test at Douglass Hanley Moir collection centres located near the fertility clinics.

### **Study procedures after the screening visit**

If you enroll in the study, you will be randomised (assigned by chance, like the flip of a coin) to receive either Hominax or placebo. You will have a 50% (1 in 2) chance of receiving Hominax and a 50% (1 in 2) chance of receiving placebo.

This is a double-blind study, which means neither you nor the study team will know which you have received. This is done to make sure the results of the study cannot be unfairly influenced by anyone. In case of an emergency, however, the study team can get this information quickly.

You will be scheduled to return for your Week 0 (Start of Study) visit approximately two weeks after the screening visit.

The **Week 0 (Start of Study) Visit** will take about 45 minutes and the following will be performed:

- Your suitability for the study will be checked and any changes to your medical history will be recorded.
- Your medical history, prior and concurrent medications, and demographics will be documented.
- Any illness or other adverse experiences over the last two weeks will be noted, as will any changes to the medications you are taking.
- You will receive study medications.

The **Week 2** phone visit will take about 15 minutes and the following will be performed:

- Your progress and compliance with study treatment will be checked.
- Any illness or other adverse experiences over the last two weeks will be noted, as will any changes to the medications you are taking.

The **Week 16** visit will take about 30 minutes and the following will be performed:

- You will provide information on your smoking and alcohol use and physical activity.
- Any illness or other adverse experiences over the last two weeks will be noted, as will any changes to the medications you are taking.
- You will need to return any unused study medications.

University of Western Sydney  
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Locked Bag 1797 Penrith NSW 2751 Australia  
[westernsydney.edu.au](http://westernsydney.edu.au)

The **Week 24** visit (or whenever your participation in the study stops) will take about 45 minutes and the following will be performed:

- You will provide information on your smoking and alcohol use and physical activity.
- Any illness or other adverse experiences over the last two weeks will be noted, as will any changes to the medications you are taking.
- You will be required to provide a fresh semen sample by masturbation for analysis.
- A 10ml (2 teaspoon) blood sample will be taken for analysis for safety monitoring (blood count, kidney and liver function) and vitamin and mineral levels.
- You will need to return any unused study medications.

The **Week 26** visit is a 10 minute post-treatment follow-up telephone visit after the end of study to see how well you have been since stopping the study treatment. It will take about 10 minutes and you will be asked to report any changes to your health or medications you have taken since the Week 24/End of Study visit.

**Please note:** If your partner becomes pregnant at any point during the study as demonstrated by a positive urine pregnancy test, you will be asked to continue your treatment and attend all scheduled visits. We will follow up on all pregnancies that occur up until three months after you stop study treatment.

The total amount of time to complete all the procedures for the study is about three hours.

### **How will I receive the study treatment?**

You will receive your study treatment as capsules in a childproof bottle. Please ensure no one else uses your study treatment and keep it out of reach of children.

Study treatment is to be taken once a day, in the morning and one hour apart from substances or supplements containing caffeine, or antibiotic medication (eg. quinolone, tetracycline, penicillin), with or without food.

### **What are the risks and possible discomforts of being in this research study?**

The ingredients included in Hominax and the inactive compounds in the placebo have all been pre-validated for safety and permitted for inclusion in oral medicines in Australia. Hominax is considered relatively safe with no drug related serious adverse events expected at the prescribed dose. Side effects are expected to be infrequent, and mostly mild to moderate in severity.

You may experience: constipation, diarrhoea, nausea, vomiting, headache, restlessness, stomach discomfort, loss of appetite, tremors, difficulty sleeping, shortness of breath, mild upper gastrointestinal tract, an allergic reaction, irritability, heartburn, chest tightness, fatigue, 'pins and needle' sensation, nosebleeds, decreased urine, rapid pulse, cough, palpitations, and increased sweating. You may

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experience some discomfort, faintness, inflammation of the vein, pain, bruising, or rarely, infection at the site of a needle stick in the process of obtaining a blood sample.

Do not exceed the prescribed dose of two capsules a day of Hominax.

You should not take Hominax if you are allergic to any of its ingredients or if you develop an allergic reaction after taking it. These symptoms include trouble breathing, or swelling of the face, mouth, lips, gums, tongue or neck, rash, hives or blisters.

Hominax may interact with Warfarin or other blood thinning medication; thyroid hormones or medications, medications for treating HIV/AIDs; barbiturates; or anti-seizure medications so it is very important that you tell the study doctor if you are taking these types of medications.

It is also very important that you tell the study doctor if you are planning to have any surgery during the study especially heart surgery such as angioplasty.

**It is important that you report all symptoms and side effects that you experience as soon as they occur, whether or not you think they are caused by the study treatment. The phone numbers for the study team are on the first page of this document.**

### **Pregnancy follow up**

If your partner becomes pregnant during the study or within three months after you have stopped taking the study treatment, please tell the study doctor immediately. Please also tell the study doctor the name and contact details of the doctor who will be taking care of your partner during the pregnancy. The study doctor will ask if your partner or your pregnancy doctor is willing to provide updates on the progress of the pregnancy and its outcome. If your partner agrees, this information will be collected for safety monitoring follow-up. You should continue taking the study supplement as normal following the schedule described earlier.

### **Are there any special instructions to follow while in this study?**

- Prior to providing a semen sample, you must abstain from sexual activity (either sexual intercourse or masturbation) for between two to three and seven days.
- It is important that you cease all vitamin supplements and complementary medicines, including traditional Chinese medicine treatment, for the duration of the study.

### **What happens if I am injured as a result of taking part in this research study?**

While Max Biocare does not expect you to suffer any health problems by taking part in this trial, Max Biocare may compensate anyone whose health suffers as a result of participation in this trial. You do not have to prove it was anyone's fault; if the health problem arose because of your participation in this trial, you will be compensated.

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### **Is being in the study voluntary?**

Yes. Taking part in this research study is up to you. You may choose not to take part or you can change your mind and withdraw (drop out) later. There will be no penalty, and you won't lose any benefits you receive now or have a right to receive. If you leave the study for any reason, the study doctor may ask you to have study procedures described for the **Week 24** visit.

If you withdraw or are removed from the study, biological samples (for example, blood or semen samples) that have been collected from you can be withdrawn if they have not yet been analysed or destroyed. If you want your samples withdrawn, you must tell the study team before or at the time you leave the study.

### **What will I have to pay for if I take part in this research study?**

There will be no charge to you for your participation in this study. The study treatment, study-related procedures, and study visits will be provided at no charge to you.

### **Will I be paid for taking part in this research study?**

You will not receive payment for taking part in this study. You may claim nominal expenses for your visits to the study clinic up to \$50 per visit without receipts, and up to \$100 a visit if receipts for travel expenses are provided.

### **If I take part in this research study, how will my privacy be protected?**

With your consent your family doctor (General Practitioner) will be told that you have decided to take part in this study. Your records obtained while you are in this trial, as well as related health records, will remain strictly confidential at all times. However, these may need to be made available to others working on behalf of NICM Western Sydney University, Max Biocare, the Human Research Ethics Committee members and Medicines Regulatory Authorities.

By signing the consent form you agree to this access for the current trial and any further research that may be done. However, we will take steps to protect your personal information and will not include your name on any sponsor forms, reports, publications, or in any future disclosures. If you withdraw from the study, we will no longer collect your personal information, but we may need to continue to use information already collected. Personal data which may be sensitive (eg., date of birth) will be collected and processed, but only for research purposes in connection with this trial.

Please note that the minimum retention period for data collected in a clinical trial in Australia is 15 years. The information you supply or about you will be stored securely and it will be de-identified before it is made to available to any researcher outside the study team.

### **Where can I find additional information about this study or published research results?**

All study tests will be analysed together once all the men required have been recruited to the study and completed treatment. The investigative team will inform participants by letter of the outcomes of the study.

### **What specific benefits will I receive for participating?**

It is possible that sperm health may improve because of study treatment or because of your visits to the research site. However, there is no guarantee that you will benefit in any way. Information from this study may help other people in the future.

### **How is the study being paid for?**

The study is being sponsored by Max Biocare Pty Ltd an Australian registered company.

### **What if I require further information?**

Please contact Professor Caroline Smith on 02 4620 3777 should you wish to discuss the research further before deciding whether or not to participate.

### **What if I have a complaint?**

This study has been approved by the Western Sydney University Human Research Ethics Committee. The Approval number is *H11411*.

If you have any complaints or reservations about the ethical conduct of this research, you may contact the Ethics Committee through the Office of Research Services on Tel +61 2 4736 0229 Fax +61 2 4736 0013 or email [humanethics@uws.edu.au](mailto:humanethics@uws.edu.au). Any issues you raise will be treated in confidence and investigated fully, and you will be informed of the outcome. If you agree to participate in this study, you will be asked to sign the Participant Consent Form.

## Participant Consent Form

This is a project specific consent form. It restricts the use of the data collected to the named project by the named investigators.

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I acknowledge that:

1. I have read and understood the Patient Information Sheet dated 29 Nov 2016 for the above Study and have had the opportunity to ask questions.
2. I understand that my participation is voluntary and that I am free to withdraw without giving any reason, without my medical care or legal rights being affected.
3. I understand that others working on NICM Western Sydney University and Max Biocare's behalf, the Independent Ethics Committee and Medicines Regulatory Authorities will need my permission to look at my health records both in respect of the current Study and any further research that may be conducted in relation to it, even if I withdraw. I agree to this access.
4. I consent to the collection, processing, reporting and transfer within Australia of my personal and sensitive data for healthcare and/or medical research purposes.
5. I agree not to restrict the use of any data or results, which arise from this Study.
6. I agree to take part in the above Study.

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Printed name of subject

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Signature of subject

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Date

**Please date your own signature at the time of signing.**

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Printed name of investigator obtaining consent

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Signature of investigator obtaining consent

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Date

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