WHAT FACTORS AFFECT ANTI-MULLERIAN HORMONE LEVELS IN MEN

Would you like to contribute to new research in men’s health?

The study aims to collect information on an important male hormone that has not been widely studied. You can participate by donating a small sample of extra blood when you have your routine blood tests and by providing some de-identified health information.

**Dr David Millar** is chief investigator and contact for this study. Contact the WA Sexual Health Centre on (08) 9389 1400 if you would like to participate.

*Co-investigators: Dr David Prentice (Royal Perth Hospital) and Associate professor Narelle Hadlow (PathWest Laboratory Medicine)*

*Approved by the Hollywood Private Hospital Research Ethics Committee. Any concerns regarding the study, contact Dr Terry Bayliss on 9346 6345*
Participants Information Sheet

What factors affect Anti-Mullerian Hormone levels in men?
This study aims to assess whether testosterone (androgen) therapy or other health factors affect Anti-Mullerian Hormone (AMH) in adult men. AMH is made by the testis and its role in early male development is important. However, factors affecting AMH in adult men are poorly understood and have not been well studied.

Background
AMH can be measured in a simple blood test. Usually male testicular function is checked by measuring testosterone levels and semen analysis. AMH may provide further helpful information on testicular function and if found to be un-affected by common medications and variations in health, it may prove to be a useful marker of testicular function including that of Sertoli testicular cells. It may be that AMH may be able to replace tests such as semen analysis in future. But it is not yet clear if other common factors such as general health, smoking, weight or androgen therapy can affect AMH levels significantly. To be able to use AMH effectively, we must first understand what factors might influence levels.

Purpose of study
The study aims to measure AMH levels in men having assessment and management of testicular function by a male sexual health clinic – WA Sexual Health Centre.

The aim is to establish ranges for AMH in adult men prior to and during any androgen (testosterone) therapy. We would like to collect data on factors that might have minor effects on AMH (smoking history, weight and height, medications) and on factors that might have more significant effects on AMH levels – general testicular function and androgen therapy.

Who can take part
Male patients who come to the WA Sexual Health Centre that are offered androgen therapy as part of their management will be invited to participate in this study if the doctor believes they may be suitable. Any decisions about therapy and management will not be influenced by this study.

For inclusions in the study you must be:
Over the age of 18 years. Have stable general health (acute illness may affect testicular function). Able to read and understand the Participant Information and Consent form; we are unable to offer interpretative services to translate the information in another language. Sign the form in front of a witness (doctor or staff member).

What is involved
Participants are asked to consent to providing an extra 5 mls of blood for AMH when undergoing routine blood tests at the request of their doctor. The usual assessment, testing and management of these men will not be impacted or altered in any way by this study. We would also ask men to donate an extra tube for AMH at any follow-up routine blood tests requested by their doctor for a period of up to 6 months (we estimate this may be up to 3-4 times over the period). The timing of these tests is, however, at the requesting doctor and patient’s discretion. The study will not impact on any timing or frequency of blood tests.

Participants are free to withdraw from this study at any time without providing a reason. Please advise Dr David Millar as soon as possible if you decide to withdraw, so that blood samples can be removed from the study and destroyed immediately. All other data will also be destroyed.
Details of the participant’s health will be de-identified and remain confidential.
We ask that participants give their doctor permission to retain de-identified information about their general health - information that is part of the usual sexual health assessment - no extra information or assessment will be performed for this study. This will include where available; weight, height, whether the participant is a smoker or not, blood pressure, medications taken and other factors related to testicular health. The doctor will retain these details in an excel spread sheet under each participants name. A study number will be allocated to each participant. Only study numbers and health details will be provided to the rest of the research group.
AMH results will be returned to the doctor to include in this data set. AMH levels will not be provided to the participants as these results will not be significant to their therapy; the clinical significance of any possible variations found would not be clear yet.

Participants’ personal health details will be de-identified and all the data, including AMH results, will be kept confidential.
This study is independent of any management by the WA Sexual Health Centre. Pathology requested by the doctor for the patient’s routine assessment and management will be sent to the pathology provider nominated by the doctor/patient and will be billed and managed in the standard manner of that provider.
AMH usually costs $50 (no Medicare rebate). A separate request form for AMH will be attached to the routine pathology requests and AMH samples will be sent separately to PathWest laboratory. There will be no charge to study participants for the AMH test done by PathWest. Blood samples for AMH will be destroyed once the study is complete.

Evidence for the utility of this study.
Literature on AMH in women has recently found that oestrogens can falsely suppress AMH levels and lead to spurious interpretation of results. It is now clear that baseline levels of AMH in women should be taken when women are not taking hormonal therapy. (Ref 1, 2) Similarly, recent studies have found associations between lower AMH levels in women and smoking and obesity. (Ref 3, 4)

It is likely that similar effects may be present in men and this study aims to clarify if this is the case.
If similar changes in men on testosterone occur, as in women on oestrogens, it would be important to clarify this before using this test to assess testicular function

References:
1. Ovarian reserve parameters: a comparison between users and non-users of hormonal contraception

2. Quantifying effect of combined oral contraceptive pill on functional ovarian reserve as measured by serum anti-Mullerian hormone and small antral follicle count using three-dimensional ultrasound

3. Elevated body mass index is associated with lower serum anti-mullerian hormone levels in infertile women with diminished ovarian reserve but not with normal ovarian reserve.

4. The physiology and clinical utility of anti-Mullerian hormone in women
Participation Consent Form – to be completed by the participant of the study (please tick the appropriate box)

What factors affect Anti-Mullerian Hormone levels in men?

Investigator: Dr David Millar

1. Have you read the information sheet about this study?  
2. Have you had an opportunity to ask questions and discuss this study?  
3. Have you received satisfactory answers to all your questions?  
4. Have you received enough information about this study?  
5. Which doctor or other researcher has spoken to you about this study?  
6. Do you understand that you are free to withdraw from this study at any time without giving a reason and without affecting your current or future medical care?  
7. Do you agree to take part in this study?  
8. Have you received a copy of the information sheet and consent form?

You will be given a copy of this consent form

Participant’s name ___________________________ Participant’s signature ___________________________ Date ____________

Witness’ name ___________________________ Witness’ signature ___________________________ Date ____________