

PI Dr Channa Jayasena



Investigative Medicine
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Dear Participant,

I am leading a new research study funded by the National Institute of Health Research, which is part of the NHS. I am writing to invite you to take part.

Men with obesity are more likely to experience problems starting a family (infertility) than other men. Unfortunately, there is currently no drug available to improve the fertility of men with obesity. We want to work out if weight loss could be used to boost the fertility of obese men.

If you decided to take part, you would receive payment for your expenses in taking part and a personal programme of weight loss delivered by a doctor at our hospital.

I would be grateful if you could read through the Participant Information Sheet, and contact us if you are interested in taking part.

If you are interested in taking part, please e-mail Dr. Aditi Sharma on reproendocrine@gmail.com

Thank you so much for reading this.

A handwritten signature in blue ink, appearing to read "Channa Jayasena".

Dr. Channa Jayasena PhD FRCP FRCPath
Consultant in Endocrinology & Head of Andrology (Male Fertility)
Imperial College Healthcare NHS Trust

Information Sheet for Research Participants

Study title: Title of project: Investigating physiological effects of weight loss on male fertility (Part 3)

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends, relatives and your GP if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Even after consenting you are free to withdraw at any time without explanation.

What is the purpose of the study?

Many men are affected by having lower than normal levels of sperm function (sometimes called 'infertility'), but very little is known about what can be done to increase levels of sperm function. Obesity is a major cause of male infertility and there is a persistent need to improve the treatment of men with this condition. We want to determine if the function of sperm changes temporarily when certain lifestyle factors such as weight management, are modified. This research will help us to understand more about fertility in men, and could improve the treatment of couples with problems starting a family.

Why have I been chosen?

We are asking men aged 18-60 to participate. We want to learn if weight loss can affect aspects of your fertility, such as your sperm count. You may not be able to take part in this study if you have:

1. Previous surgery to your testicles
2. Mumps infection
3. Hormone replacement therapy
4. Previous cancer
5. Taking medications which might affect your fertility
6. Any chronic illness
7. An occupation requiring strenuous physical exercise that may require a high energy diet

Do I have to take part?

No, it is up to you. We are required to give you a minimum of 24 hours to decide whether you wish to take part, however you can take as long as needed to decide. If you decide to take part, you will be asked to sign a consent form. You are free to withdraw from the study at any time without giving a reason. If you withdraw from the study, any identifiable data or tissue already collected with consent, would be retained and used in the study. No further data or tissue would be collected, or any other research procedures carried out.

What will happen to me if I decide to take part?

We would ask you to attend up to eight visits at the Andrology Unit, Hammersmith Hospital. The whole study will last up to 16 weeks duration. Each visit will take 30-60 minutes, and a member of the research team will:

1. Ask questions about your medical history at the first visit and support you with advice on diet throughout the remaining study visits.
2. Measure your height, weight, blood pressure during each visit. The size of your testicles will only be measured at the first visit; it is a simple and painless exam, and routinely performed in clinic to assess men with fertility problems.
3. Take a blood sample to measure levels of your reproductive hormones (like testosterone), and measure your body's metabolism (like your cholesterol and sugar levels).
4. Ask you to produce a semen sample into a sterile container to test its concentration and quality. You will be given time to produce this in a chosen private room in the Andrology Department, Hammersmith Hospital.
5. Distribute a validated questionnaire to assess your quality of life at the beginning of and final week of the study period only.
6. Contact you up to 24 months after completion of the study you decided to take part to enquire if pregnancy has occurred.

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65 During the first visit, we will confirm your suitability for the study. During the study, you will be asked to follow
66 a dietary programme for up to 16 weeks. You will be randomized to one of two diets. This means there is a
67 50% chance you will be asked to take prepacked products to replace normal meals, and a 50% chance you
68 would get NHS advice on healthy eating. We will provide all training and liquid diet products to complete the
69 study.

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71 **What are the side effects of taking part?** You may experience pain or mild discomfort from giving a blood
72 sample, which involves inserting a needle into your arm to withdraw blood. Weight loss programmes with low
73 energy diet are readily available without prescription, and avoid problems of starving since participants
74 continue to receive controlled levels of food nutrients and calories. Nevertheless, any weight loss will be
75 monitored by the research team during the study. Possible side effects from low energy diet are usually
76 minimal. They may include constipation or diarrhoea, headache, nausea and rarely gallstones.

77 **What are the possible disadvantages and risks of taking part?** Some people may find questions about
78 their health, giving a semen sample, and having a testicular examination slightly embarrassing. However,
79 these will be performed in a department with health care professionals who routinely deal with these
80 procedures. All information and results from the study will be kept strictly confidential, and only used by
81 researchers involved in the study. If we identify any fertility or metabolic health problems, which have not
82 been identified previously, we would facilitate referral by your GP for standard NHS treatment.

83 **What are the possible benefits of taking part?** The purpose of this study is to investigate if weight loss
84 temporality improves sperm function, but there is currently no evidence to suggest that this will change your
85 fertility. However, all participants will benefit from weight loss. Nevertheless, your participation may help us
86 to understand more about infertility in obese men, and could improve the diagnosis and treatment of couples
87 affected by infertility in the future.

88 **What if new information becomes available?** Sometimes during the course of a research project, new
89 information becomes available. If this happens, your research doctor will tell you about it and discuss with
90 you whether you want to continue in the study. If you decide to continue in the study, you will be asked to
91 sign an updated consent form. Alternatively, on receiving new information your research doctor might
92 consider it to be in your best interests to withdraw you from the study.

93 **What happens when the research study stops?** Once the study has finished, a summary of the results of
94 the study can be made available to you should you wish. If you have any problems immediately following the
95 study, then you should contact the research team using the numbers provided.

96 **What if something goes wrong?** Imperial College London holds insurance policies applying to this study.
97 If you experience serious and enduring harm or injury as a result of taking part in this study, you may be
98 eligible to claim compensation without having to prove that Imperial College is at fault. This does not affect
99 your legal rights to seek compensation. If you are harmed due to someone's negligence, then you may have
100 grounds for a legal action. Regardless of this, if you wish to complain, or have any concerns about any
101 aspect of the way you have been treated during the course of this study then you should immediately inform
102 the Chief Investigator (Dr. Jayasena – please see contact details at end of this form). The normal NHS
103 complaint procedure is also available to you, by contacting the Patient Advice and Liaison Service (PALS) of
104 Imperial College Healthcare NHS Trust on 020 3313 0088 or email imperial.PALS@nhs.net. If you are still
105 not satisfied with the response, you may contact the Imperial Joint Research Compliance Office.

106 **Will my taking part in this study be kept confidential?** All information collected about you during the study
107 will be kept strictly confidential. Information security measures are in place at all times according to Imperial
108 College's Information Security Policy. Information in paper form will be held in locked offices within Imperial
109 College Faculty of Medicine, Hammersmith Hospital. Technical measures, for example use of encryption
110 tools will be used to protect information held in electronic form. This data will be accessible to study
111 investigators. Information will be stored for 10 years according to Imperial College Data Management policy
112 and will follow the principles as set out in the Data Protection Act 1998.

113 **Who will have access to my personal data during the study?** NHS clinicians working on this research
114 study who are or may be not part of your usual care team will have access to your medical records, for the

115 purposes of this study. Also authorised persons from the sponsor, NHS and regulatory authorities may have
116 access to your medical records.

117 **What will happen to my blood samples during the study?** All samples will be anonymised with a unique
118 study code, and stored in Andrology Department, Imperial College Healthcare NHS Trust. Samples will be
119 analysed in Imperial College Healthcare NHS Trust and disposed after the study has finished.

120 **What will happen to the results of the research study?** The results are likely to be published in the six
121 months following the completion of the study. Your confidentiality will be ensured at all times and you will not
122 be identified in any publication.

123 **Will my GP be notified?** You will be asked to provide your GP contact details at your initial screening visit,
124 so your GP can be notified by a standard letter. Your GP will be informed of incidental findings and will be
125 given contact details of the study investigators in case they have further questions.

126 **What will happen to me if I lose capacity during the study?** In case you lose capacity during the study
127 you will be withdrawn from the study. Identifiable data or tissue already collected with consent would be
128 retained and used in the study. No further data or tissue will be collected, or any other research procedures
129 carried out.

130 **Expenses** We are able to offer expenses of £25 for a screening appointment. We are also able to offer £50
131 for the other visits, which last up to 90 minutes each. You will therefore receive total reimbursement of £550
132 for completing the study. This payment will include reimbursement for travel, parking costs etc.

133 **Who is organising and funding the research?** This study is organised by Imperial College London and
134 funded by the National Institute for Health Research (NIHR). Commercially available product would be
135 provided free of charge, with no role in designing or influencing the conduct of the study.

136 **Who has reviewed the study?** This study has been reviewed by the London – Queen Square Research
137 Ethics Committee.

138 **Contact for Further Information:** If you experience any problems during the study, you may withdraw at
139 any stage. The doctor leading the study, Dr Channa Jayasena, can be contacted on 020 8383 3242, or by e-
140 mail (c.jayasena@imperial.ac.uk).