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Changes in male fertility during chronic illness

Submission date
24/02/2017

Recruitment status
No longer recruiting

Registration date
05/04/2017

Overall study status
Completed

Last Edited
18/03/2025

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Many men are affected by having lower than normal levels of sperm function and subsequent infertility, but very little is known about the cause and what can be done to increase levels of sperm function. This study is looking at whether male infertility can be affected by various chronic (long-term) diseases such as diabetes or obesity, by changing levels of reproductive hormones and sperm count. This research will help to understand more about infertility in men, and could improve the diagnosis and treatment of couples affected by infertility in the future. This study is made up of two parts. The first part of the study aims to look at whether there are any natural indicators of infertility in men with long-term diseases and healthy men of the same age. The second part of this study is looking at whether additional lifestyle advice about lowering risk factors (such as weight or smoking) can help infertile men with long-term diseases.

Who can participate?
In the first part of the study, healthy men and men with long-term diseases such as diabetes or obesity can take part. In the second part of the study, men with long-term diseases who are infertile can take part.

What does the study involve?
During the first part of the study participants attend the Andrology Unit, Hammersmith Hospital, to answer questions about their medical history, have their height and weight measured, give a blood sample to analyse hormone levels and produce a semen sample to test their sperm count. During the second part of the study, participants are randomly allocated to receive either additional lifestyle advice or no additional lifestyle advice above and beyond what is given in the NHS for up to 16 weeks. They are asked to attend up to four further visits over the study period. Each visit will take 30-60 minutes, and will consist of questions about their medical history, measurements of height and weight, providing blood samples to analyse hormone levels and producing a semen sample to test sperm count. If participants are in the Additional Lifestyle Advice group, a member of the study team spends 30 minutes of these appointments advising participants how to reduce lifestyle factors known to affect fertility.

What are the possible benefits and risks of participating?
There are no direct benefits involved with participating however the study should help to improve the researcher’s understanding of infertility in men which could help future patients. Results of the tests performed during this study may indicate problems with fertility which may

require further medical assessment. In this case, participants will be referred for the appropriate medical care that would be offered to an NHS patient and we would provide any information that would help the referral. Some participants may experience pain or mild discomfort from giving a blood sample which involves inserting a needle into their arm to withdraw blood. However, blood samples will be collected by a trained member of the research team who is experienced in taking bloods. All information and results from the study will be kept strictly confidential, and only used by researchers involved in the study.

Where is the study run from?
Hammersmith Hospital (UK)

When is the study starting and how long is it expected to run for?
September 2016 to August 2023

Who is funding the study?
Imperial College Trust (UK)

Who is the main contact?
Dr Channa Jayasena
c.jayasena@imperial.ac.uk

Contact information

Type(s)
Public

Contact name
Dr Channa Jayasena

ORCID ID
https://orcid.org/0000-0002-2578-8223

Contact details
6th Floor Commonwealth Building
Hammersmith Hospital
DuCane Road
London
United Kingdom
W2 0NN
+44 20 8383 3242
c.jayasena@imperial.ac.uk

Additional identifiers

Protocol serial number
168999

Study information

Scientific Title

Investigating how chronic illness affects markers of reproductive function in men with infertility

Study objectives
The aim of this study is firstly to prospectively study if patients with chronic disease, such as diabetes and obesity, have abnormal parameters of fertility (hormone levels and sperm count). Secondly, this study will investigate if additional lifestyle advice over and above that provided in the NHS could be used to increase levels of reproductive markers in patients with known infertility.

Ethics approval required
Old ethics approval format

Ethics approval(s)
London Bridge Research Ethics Committee, 01/07/2015, ref: 15/LO/0679

Study design
Part 1: Single-centre case-control observational study
Part 2: Single-centre randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Male infertility

Interventions
Part 1 (Observational component):
Participants will be asked to attend a single visit at the Andrology Unit, Hammersmith Hospital. Visit will take approximately one and half our, and will consist of:
1. Questions about their medical history
2. Measurement of their height and weight
3. Giving a blood sample to analyse hormone levels such as testosterone
4. Producing a semen sample to test their sperm count.
A summary of the results of the study visit could be made available to the participant's GP should he wishes. No follow up is required.

Part 2 Interventional Component):
Participants with known infertility referred to Hammersmith Andrology Unit will be randomized into two sub-groups using an online tool such as random.org for a period up to 16 weeks:
Group 1: Participants receive no lifestyle advice, over and beyond what is given in the NHS.
Group 2: Participants will receive additional lifestyle advice during each study visit.
Additional Lifestyle Advice: Lifestyle advice which is over and beyond what is given in the NHS will be delivered to participants by a member of the research team, and would mirror clinical practice during fertility outpatient consultations. A 30 minute interview would be held, highlighting and monitoring progress reducing any lifestyle factors which persist despite lifestyle advice given in the NHS, such as body weight, increasing physical activity, stopping smoking and recreational drug use, and reducing excessive alcoholic intake.

Study visits 1-2:
Participants will be asked to attend up to two subsequent visits during the study period. Visits would involve brief history, weight measurement and collection of blood and semen. This would take 30 minutes to perform.

Study visits 3-5:
As described above, patients in each Group randomized to Additional Lifestyle Advice will receive lifestyle advice which is over and beyond what is given in the NHS, during each study visit. This would take an additional 30 minutes to perform.

Intervention Type
Behavioural

Primary outcome(s)
Part 1:
Sperm count abnormalities will be measured using routine semen analysis at baseline.

Part 2:
Sperm count abnormalities will be measured using routine semen analysis at baseline, 2, 3, 4 and 5 weeks.

Key secondary outcome(s))
Part 2:
1. Weight, measured using scales at baseline, 2, 3, 4 and 5 weeks
2. Serum reproductive hormones using automated immunoassays at baseline, 2, 3, 4 and 5 weeks
3. Serum metabolic parameters using automated immunoassays at baseline, 2, 3, 4 and 5 weeks

Completion date
30/08/2023

Eligibility

Key inclusion criteria
Inclusion Criteria (study 1 only)
1. Male
2. 18-60 years of age
3. Participants in the following groups will be recruited:

Control Group: Healthy participants
Disease Groups: Participants with chronic diseases e.g. diabetes mellitus, obesity

Inclusion Criteria (study 2 only)
1. Male
2. Known infertility
3. 18-60 years of age
4. Current lifestyle factors known to affect fertility (e.g. any raised BMI, smoking, recreational drug use, excessive alcohol intake) which remain despite any previous lifestyle advice gained in the NHS

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
60 years

Sex
Male

Key exclusion criteria
1. History of anaemia
2. Needle-phobia
3. Acute illness likely to affect the result of study
4. Impaired ability to provide full consent to take part in the study

Date of first enrolment
01/09/2016

Date of final enrolment
31/08/2019

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Hammersmith Hospital
Imperial College Healthcare NHS Trust,
Du Cane Road
London
United Kingdom
W12 0HS

Sponsor information

Organisation

AHSC Joint Research Compliance Office

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
Charity

Funder Name
Imperial College Trust

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for the study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results			18/03/2025	No	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes