

Changes in male fertility during chronic illness

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Registration date 05/04/2017	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 18/03/2025	Condition category Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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
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Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 measure

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.

Secondary outcome measures

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

Overall study start date

01/09/2016

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

Age group

Adult

Lower age limit

18 Years

Upper age limit

60 Years

Sex

Male

Target number of participants

50

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**

England

United Kingdom

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

Sponsor details

510A 5th Floor Lab Block
Charing Cross Hospital
Fulham Palace Road
London
United Kingdom
W6 8RF

Sponsor type

Research organisation

ROR

<https://ror.org/041kmwe10>

Funder(s)

Funder type

Charity

Funder Name

Imperial College Trust

Results and Publications

Publication and dissemination plan

Planned publication date in a high-impact peer reviewed journal.

Intention to publish date

30/08/2024

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?
HRA research summary			28/06/2023	No	No
Basic results			18/03/2025	No	No