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Investigating the regulation of male fertility

Submission date	Recruitment status	[_] Prospectively registered
15/01/2017	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
15/03/2017	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
22/01/2024	Urological and Genital Diseases	

Plain English summary of protocol

Background and study aims
Infertility is when a couple cannot get pregnant (conceive), despite having regular unprotected sex. The underlying cause of infertility is unclear in most men who suffer from the condition. The aim of this study is to find out whether male infertility can be caused by particular changes in DNA (the genetic material) and by unusual levels of reproductive hormones.

Who can participate?
Infertile men aged 18-65.

What does the study involve?
Participants are asked to complete a questionnaire and undergo blood sampling and clinical examination. A semen sample is also tested. Some participants have testicular biopsies (tissue samples from the testicles) as part of their treatment for infertility and a small amount of testicular tissue is stored. Participants are followed up over the telephone by a study investigator (clinician or nurse) on up to two occasions during the 3 years after the study.

What are the possible benefits and risks of participating?
The results of this study will advance the understanding of infertility in men, and may improve diagnostic methods and treatments for couples affected by infertility in the future. The results of the tests performed during this study could lead to incidental findings which are likely to require further medical assessment. In this case, participants are referred for the appropriate medical care that would be offered to an NHS patient. Some participants may experience pain or mild discomfort from giving a blood sample which involves inserting a needle into their arm to take blood. However, blood samples are collected by a trained member of the research team who is experienced in taking blood. All information and results from the study are kept strictly confidential and only used by researchers involved in the study.

Where is the study run from?
Imperial College Healthcare NHS Trust (UK)

When is the study starting and how long is it expected to run for?
July 2014 to March 2023

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

Who is the main contact?
Dr Channa N. Jayasena
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
156160

Study information

Scientific Title
Investigating the regulation of male fertility: an observational cohort study

Study objectives
The study aims to identify factors that may be causing male infertility. These factors will provide better understanding of male infertility and its underlying pathophysiology.

Ethics approval required

Old ethics approval format

Ethics approval(s)
West London Research & Gene Therapy Advisory Committee, 15/07/2014, ref: 14/LO/1038

Study design
Observational cohort study.

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Diagnostic

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

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

Interventions
Patients will be recruited via the Andrology department at Hammersmith Hospital, London. The aim is to recruit approximately 2000 men. Participants will be asked to complete a questionnaire, undergo blood sampling and clinical examination. A semen sample will also be analysed. Some participants have testicular biopsies as part of their treatment for infertility and a small amount of testicular tissue will be stored. Data will be processed statistically and used to highlight the key mechanisms underlying male infertility. Participants will be followed up over the telephone by a study investigator (clinician or nurse), on up to two occasions during the 3 years following study recruitment.

Intervention Type
Genetic

Primary outcome measure
Genetic/molecular abnormalities, assessed using state-of-the-art techniques at the time including Sanger sequencing, next generation sequencing, array comparative genomic hybridisation (CGH), polymerase chain reaction (PCR) and enzyme assays and/or immunoassays, at baseline

Secondary outcome measures
1. Sperm parameters, measured using routine semen analysis at baseline
2. Smoking status, measured using a questionnaire at baseline
3. Weight, measured using scales at baseline
4. Sperm count abnormalities, measured using routine semen analysis at baseline

Overall study start date
15/07/2014

Completion date
01/03/2023

Eligibility

Key inclusion criteria
1. Infertile men
2. 18-65 years of age

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Male

Target number of participants
2000

Key exclusion criteria
1. History of anaemia
2. Needle phobia
3. Impaired ability to provide full consent to take part in the study

Date of first enrolment
29/09/2014

Date of final enrolment
31/12/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Imperial College Healthcare NHS Trust
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
University/education

Funder Name
Imperial College Trust (ref: P52570)

Results and Publications

Publication and dissemination plan
The planned publication date is approximately one year after the trial end date in a high-impact peer reviewed journal.

Intention to publish date
01/03/2024

Individual participant data (IPD) sharing plan

The current data sharing plans for the current 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
Results article		01/01/2019	22/01/2024	Yes	No
Results article		06/10/2022	22/01/2024	Yes	No