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Understanding fertility in women with chronic kidney disease

Submission date
26/07/2021

Recruitment status
No longer recruiting

Registration date
28/09/2021

Overall study status
Completed

Last Edited
28/09/2021

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Chronic kidney disease (CKD) is a long-term condition where the kidneys don't work as well as they should. Rates of CKD continue to rise in women of reproductive age, with 15% of patients less than 50 years old. This study aims to investigate how CKD affects the reproductive system, ovarian reserve (the number and quality of eggs) and inflammation. It also aims to investigate if increasing the intensity of dialysis improves fertility.

Who can participate?
Women aged 18-49 years with chronic kidney disease, or women between 18-49 years old with no medical history and no active or previous disease/treatment which could have affected their fertility.

What does the study involve?
The study will involve a minimum of one and a maximum of three visits. At each visit blood samples will be taken and a transvaginal scan will be carried out.

What are the possible benefits and risks of participating?
Participation will help the researchers to improve the care for women with kidney disease who have fertility problems. A fertility specialist will contact participants to give them their results, explain what they mean and how best to act on them if there is a problem. Their GP will be informed of any findings and if they need emotional support counsellors will be available as part of the study. There are no risks of taking part. The transvaginal ultrasound scan is safe and has no significant risks associated with it. Occasionally there is minimal discomfort during the scan but participants' wellbeing will be the upmost priority during the scan.

Where is the study run from?
King’s Fertility, London (UK)

When is the study starting and how long is it expected to run for?
March 2000 to April 2023

Who is funding the study?
The Fetal Medicine Foundation (UK)

Who is the main contact?
Mahua Bhaduri
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Contact information

Type(s)
Scientific

Contact name
Dr Mahua Bhaduri

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
285546

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 49608, IRAS 285546

Study information

Scientific Title
Fertility Evaluation in ReNal disease (FERN)

Acronym
FERN

Study objectives

1. Patients with chronic kidney disease (CKD) will have reduced ovarian reserve compared to healthy controls. This will be demonstrated by blood markers and a transvaginal scan
2. Female CKD patients will have dysregulation of the hypothalamic-pituitary-ovarian (HPO) axis
3. Inflammatory markers in CKD women will be higher than normal controls

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 13/07/2021, London - Hampstead Research Ethics Committee (Ground Floor, Temple Quay, House 2, The Square, Bristol, BS1 6PN, UK; +44 (0)207 104 8345, +44 (0)207 104 8328; hampstead.rec@hra.nhs.uk), REC ref: 21/PR/0754

Study design
Observational; Design type: Cross-sectional

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Chronic kidney disease

Interventions
Study design: Multi-centre prospective observational cohort with blood sample collection and transvaginal ultrasound.

Setting: specialist renal clinics in the UK

Study duration per participant: Up to 6 months

Patients will be contacted and asked to fill in a patient questionnaire and sign patient consent forms.

Patients who have CKD and are not starting intensive haemodialysis will have at least one visit and a maximum of three visits with blood tests and a transvaginal scan at King's Fertility.

Patients who will be starting on haemodialysis will have three visits/sample collection times: prior to starting HD treatment, at 3 months of treatment and at 6 months. They will be also offered a transvaginal scan at each visit at King's Fertility.

All patients will be asked to fill out a validated questionnaire on how fertility impacts their quality of life.

Intervention Type
Other

Primary outcome measure
1. Fertility assessed using blood markers (AMH, oestradiol, FSH, LH, progesterone, testosterone) and transvaginal ultrasound scan at baseline, 3 months and 6 months

Secondary outcome measures
1. The relationship of infertility, chronic kidney disease and chronic inflammation investigated using blood markers (O-link inflammatory panel) at baseline, 3 months and 6 months
2. Quality of life measured by a qualitative survey at baseline

Overall study start date
01/03/2000

Completion date
01/04/2023

Eligibility

Key inclusion criteria
Study group:
1. Women with CKD Stages 1-5 including those with renal transplants and on dialysis
2. ≥18 years old but ≤49 years old
3. Willing and able to provide written informed consent

Control group:
1. Women aged 18-49 years
2. Male factor infertility
3. Willing and able to provide written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
49 Years

Sex
Female

Target number of participants

Planned Sample Size: 200; UK Sample Size: 200

Key exclusion criteria
Study group:
1. Pregnant patients or those who are currently breastfeeding
2. Patient who have active or previous disease/treatment which could have affected their ovarian reserve i.e. chemotherapy, radiotherapy, ovarian surgery
3. Patients who require a translator

Control group:
1. Patients who have active or previous disease/treatment which could have affected their fertility
2. Patients who have female factor infertility, i.e. tubal factor, anovulatory disorders, endometriosis, fibroids, low ovarian reserve
3. Patients who have a known medical condition
4. Patient who require a translator

Date of first enrolment
01/08/2021

Date of final enrolment
01/10/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
King's College Hospital
Denmark Hill
London
United Kingdom
SE5 9RS

Study participating centre
Leicester Royal Infirmary
Infirmary Square
Leicester
United Kingdom
LE1 5WW

Study participating centre

Royal London Hospital
Renal Department
Whitechapel Rd
Whitechapel
United Kingdom
E1 1FR

Study participating centre
NHS Nottingham North and East CCG
Gedling Civic Centre
Arnot Hill Park
Arnold
Nottingham
United Kingdom
NG5 0TE

Study participating centre
St Mary's Hospital
The Bays
South Wharf Road
London
United Kingdom
W2 1BL

Study participating centre
St Thomas' Hospital
Westminster Bridge Road
London
United Kingdom
SE1 7EH

Sponsor information

Organisation
King's College Hospital NHS Foundation Trust

Sponsor details
Mr Rahman Ahmed
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161 Denmark Hill
London

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United Kingdom
SE5 8EF
+44 (0)20 3299 1980
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Sponsor type
Hospital/treatment centre

Website
https://www.kch.nhs.uk/

ROR
https://ror.org/01n0k5m85

Funder(s)

Funder type
Charity

Funder Name
Fetal Medicine Foundation

Alternative Name(s)
FMF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The protocol will not be shared. Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
01/04/2024

Individual participant data (IPD) sharing plan

The 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?
Participant information sheet	version 2.0	21/06/2021	04/08/2021	No	Yes
Participant information sheet	PIS for control group version 2.0	21/06/2021	04/08/2021	No	Yes
HRA research summary			28/06/2023	No	No