ISRCTN23312225 https://doi.org/10.1186/ISRCTN23312225

# 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

### Integrated Research Application System (IRAS)
285546

### Central Portfolio Management System (CPMS)
49608

# 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

## Primary study design
Observational

## Study design
Observational; Design type: Cross-sectional

## Study type(s)
Other

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

## Key secondary outcome(s)
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

### 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

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 Years

### Upper age limit
49 Years

### Sex
Female

### 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**
United Kingdom

England

**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

**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

### 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? |
|---|---|---|---|---|---|
| HRA research summary | | | 28/06/2023 | No | No |
| 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 |