

# Serum hormone levels in women with chronic pain

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| <b>Submission date</b><br>15/01/2015   | <b>Recruitment status</b><br>No longer recruiting     | <input type="checkbox"/> Prospectively registered    |
|  |   | <input type="checkbox"/> Protocol                    |
| <b>Registration date</b><br>10/04/2015 | <b>Overall study status</b><br>Completed              | <input type="checkbox"/> Statistical analysis plan   |
|  |   | <input type="checkbox"/> Results                     |
| <b>Last Edited</b><br>29/12/2021       | <b>Condition category</b><br>Musculoskeletal Diseases | <input type="checkbox"/> Individual participant data |
|  |   | <input type="checkbox"/> Record updated in last year |

## Plain English summary of protocol

### Background and study aims

Long-term pain is a major public health issue. In the UK, about 7•8 million people live with chronic pain and someone is in pain in more than a third of the households. The aim in this study is to further our understanding of the mechanism of pain in women with long-term pain and to inform the design of future clinical trials of sex steroid hormones for pain relief.

### Who can participate?

Women who have had pain for at least 6 months, aged 18–50

### What does the study involve?

Participants will attend one hospital visit to complete a questionnaire and give a blood sample for the measurement of hormone levels.

### What are the possible benefits and risks of participating?

There are no benefits. The risks might be brief pain associated with the blood test and difficulty answering the questions on the study questionnaire because chronic pain is associated with psychological distress.

### Where is the study run from?

Oxford University Hospital (UK)

### When is the study starting and how long is it expected to run for?

March 2015 to December 2017

### Who is funding the study?

Medical Research Fund (UK)

### Who is the main contact?

Dr Katy Vincent, [katy.vincent@wrh.ox.ac.uk](mailto:katy.vincent@wrh.ox.ac.uk)

## Contact information

### Type(s)

Scientific

**Contact name**

Dr Katy Vincent

**Contact details**

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**Additional identifiers****Protocol serial number**

N/A

**Study information****Scientific Title**

Serum hormone levels in women with chronic pain in the Women In Pain Studies, Oxford: a cohort study

**Acronym**

WIPSOx1

**Study objectives**

To what extent is the hormone profile altered in women with chronic pain altered?:

1. Specifically, what proportion of women are hypoestrogenic, hypoandrogenic and hypocortisolaemic?
2. Do clinical symptoms relate to the extent of hypothalamic-pituitary-ovarian (HPO) /hypothalamo-pituitary-adrenal (HPA) axis suppression?

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

NRES Committee South Central - Oxford B, 26/01/2015, ref: 15/SC/0077

**Study design**

Single centre observational cohort study

**Primary study design**

Observational

**Study type(s)**

Screening

## **Health condition(s) or problem(s) studied**

Chronic pelvic and chronic musculoskeletal pain

## **Interventions**

Women will attend a single dedicated research appointment and will

1. Complete a questionnaire assessing the severity, nature and location of their pain; regularity of their menstrual cycle; levels of perceived stress; psychological well being; and a brief focused medical history.
2. Have height and weight measurements and calculation of their body-mass index
3. Have a blood sample taken for analysis of hormone levels: oestradiol, progesterone, testosterone, follicle-stimulating hormone (FSH), cortisol and sex-hormone binding globulin (SHBG)
4. Have vitamin D levels measured

## **Intervention Type**

Other

## **Primary outcome(s)**

Hormonal profiles of women with chronic pain:

1. Oestradiol
2. Progesterone
3. Testosterone
4. FSH
5. Cortisol
6. SHBG

## **Key secondary outcome(s)**

Relation between disease characteristics and suppression of HPO and HPA axes (hormone profiles and measures of pain severity and duration)

1. Numeric rating scales (NRS) will be used to measure average daily pain and most severe pain.
2. A body map will be used to visually identify the location of pain(s).
3. Validated measures will be used to measure psychological state cognitive processes:
  - 3.1. STAI – State and trait anxiety questionnaires
  - 3.2. Beck depression inventory (BDI)
  - 3.3 McGill pain questionnaire, short form (SF-MPQ2)
  - 3.4 Pain Catastrophising scale (PCS) will also be used

## **Completion date**

31/07/2019

## **Eligibility**

### **Key inclusion criteria**

1. Willing and able to give informed consent
2. Age 18–50
3. Pelvic or musculoskeletal pain (back, hip or knee or fibromyalgia) for more than 50% of the days per month for at least the past 6 months

### **Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

Female

**Total final enrolment**

101

**Key exclusion criteria**

1. Use of exogenous hormones for any reason (including contraception, hormone-replacement therapy and treatment of pain), except women with pelvic pain who may be included if they have a Mirena intrauterine system in place
2. Use of mild opiates (e.g., codeine phosphate or tramadol) for 50% of the days per month
3. Use of strong opiates in the past 6 months
4. Previous hysterectomy or bilateral oophorectomy
5. Confirmed or suspected pregnancy
6. Pregnant within the past 6 months or currently breastfeeding
7. Recreational opiate use in the past 6 months
8. Any other significant disease or disorder which, in the opinion of the Investigator, may either put the participants at risk because of participation in the trial, or may influence the result of the trial, or the participant's ability to participate in the trial

**Date of first enrolment**

01/01/2015

**Date of final enrolment**

31/12/2016

## **Locations**

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Oxford University Hospital**

Nuffield Department of Obstetrics and Gynaecology

Level 3

Women's Centre

Headington  
Oxford  
United Kingdom  
OX3 9DU

## Sponsor information

### Organisation

University of Oxford (UK)

### ROR

<https://ror.org/052gg0110>

## Funder(s)

### Funder type

Research organisation

### Funder Name

Medical Research Fund (UK)

## Results and Publications

### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Katy Vincent, [katy.vincent@wrh.ox.ac.uk](mailto:katy.vincent@wrh.ox.ac.uk).

### IPD sharing plan summary

Available on request

### Study outputs

| Output type                                   | Details                       | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|-------------------------------|--------------|------------|----------------|-----------------|
| <a href="#">HRA research summary</a>          |                               |              | 26/07/2023 | No             | No              |
| <a href="#">Participant information sheet</a> | Participant information sheet | 11/11/2025   | 11/11/2025 | No             | Yes             |