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Serum hormone levels in women with chronic pai

Submission date	Recruitment status	[ ] Prospectively registered
15/01/2015	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
10/04/2015	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
29/12/2021	Musculoskeletal Diseases	[ ] 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

Contact information

Type(s)
Scientific

Contact name
Dr Katy Vincent

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Screening

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

Health condition(s) or problem(s) studied
Chronic pelvic and chronic muscloskeletal 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 measure
Hormonal profiles of women with chronic pain:
1. Oestradiol
2. Progesterone
3. Testosterone
4. FSH
5. Cortisol
6. SHBG

Secondary outcome measures
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 – Stait 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

Overall study start date
01/03/2015

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

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
200

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
England

United Kingdom

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)

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Sponsor type
University/education

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Research organisation

Funder Name
Medical Research Fund (UK)

Results and Publications

Publication and dissemination plan
Findings will be disseminated via peer-reviewed publications and presentation at relevant pain, gynaecology and endocrinology meetings. The plan is to submit the manuscript to an appropriate journal within 3 months of completion of the study.

Intention to publish date
01/06/2022

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.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			26/07/2023	No	No