ISRCTN17271094 https://doi.org/10.1186/ISRCTN17271094

Investigating the effects of the hormone kisspeptin on human brain activity

Submission date
28/10/2020

Recruitment status
No longer recruiting

Registration date
29/10/2020

Overall study status
Completed

Last Edited
06/02/2023

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Hypoactive Sexual Desire Disorder (HSDD) is characterised by a lack or absence of sexual fantasies and desire for sexual activity. Studies estimate that in the UK HSDD affects 17-40% of men and women, making it one of the most common sexual health complaints. HSDD can result in devastating distress, interpersonal difficulties and detrimental effects on a person's physical and mental wellbeing. Importantly, kisspeptin is an essential reproductive hormone with established roles in controlling human sexual and emotional brain activity, therefore it may have a vital role in HSDD.

Who can participate?
We are looking for men and women who are concerned by low sexual desire and who are aged >18 years, heterosexual, right-handed and in a relationship for at least 6-months. Interested men and women who meet these criteria will be asked to complete a three-stage recruitment process (i. self-reported questionnaire, ii. telephone screening, iii. face-to-face appointment) to confirm eligibility.

What does the study involve?
The study consists of an initial screening visit followed by 2 weekday 4-hour visits. You will receive an injection of a natural and safe hormone (called Kisspeptin), give blood samples, answer some questionnaires and have an MRI scan with physiological monitoring (no radiation).

What are the possible benefits and risks of participating?
Despite its significant burden, medical and psychological treatments have shown only modest benefit. This indicates a need to better understand the underlying sexual and emotional brain activity in HSDD (in order to help develop more effective treatments), which this study will help address. Whilst kisspeptin is a naturally occurring hormone, which has been given safely to > 500 men and women without side effects (by our groups and others), a team of senior doctors will supervise visits with appropriate safety monitoring.

Where is the study run from?
The initial screening visit is held at Charing Cross Hospital (Hammersmith, London), followed by two study visits at Hammersmith Hospital (White City, London) (UK)

When is the study starting and how long is it expected to run for?
June 2017 to December 2022

Who is funding the study?
1. Medical Research Council (UK)
2. NIHR Clinical Research Facility (UK)
3. NIHR Biomedical Research Centre at Imperial College Healthcare NHS Trust (UK)

Who is the main contact?
Professor Waljit Dhillo. The team can be contacted on Imperial.MaleHSDD@nhs.net (male enquiries) and Imperial.FemaleHSDD@nhs.net (female enquiries)

Study website
https://www.imperialhsdd.com/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
232585

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 232585

Study information

Scientific Title
Physiological studies to investigate the effects of kisspeptin on human brain processing

Study objectives
Kisspeptin modulates brain activity and related behaviours in men and women with low sexual desire via key limbic brain regions.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 12/10/2017, London Riverside Research Ethics Committee (Chelsea & Westminster Hospital, 369 Fulham Road, London, SW10 9NH, United Kingdom; +44 (0)20 7104 8112; riverside.rec@hra.nhs.uk) ref: 17/LO/1504.

Study design
Randomized double-blinded two-way crossover placebo-controlled study

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Other

Study type(s)
Other

Participant information sheet
https://www.imperialhsdd.com/

Health condition(s) or problem(s) studied
Investigation of brain processing in Hypoactive Sexual Desire Disorder

Interventions
Randomised, double-blinded, two-way crossover study comparing the effects of a 75-minute intravenous infusion of kisspeptin at 1 nmol/kg/hour versus vehicle (rate-matched intravenous infusion of Gelofusin) on sexual and emotional brain processing (as determined using functional MRI [fMRI]) in men and women with Hypoactive Sexual Desire Disorder.

The order of the infusions will be randomized (using www.randomizer.org) and participants will be blinded to the identity of the infusions.

Intervention Type
Biological/Vaccine

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Kisspeptin

Primary outcome measure
Sexual and emotional brain processing during validated fMRI tasks (such as male/female facial images and erotic videos), as determined by the change in fMRI blood oxygen level dependent (BOLD) activity measured once in each infusion condition

Secondary outcome measures
Measured during intravenous infusion of kisspeptin or vehicle:
1. Hormone and biochemical concentrations, including levels of luteinising hormone, follicle-stimulating hormone, kisspeptin, oestradiol, testosterone, measured every 15-minutes using a blood sample
2. Psychometric measure of motivation determined using the Behavioral Inhibition/Activation System Scale
3. Psychometric measure of sexual arousal and desire determined using the Sexual Arousal & Desire Inventory
4. Psychometric measure of mood determined using the Positive and Negative Affect Schedule
5. Psychometric measure of anxiety and attention determined using the State-Trait Anxiety Inventory and D2 Test of Attention
6. Physical measures of sexual arousal and safety, including blood pressure (sphygmomanometer) and heart rate (pulse oximeter)

Overall study start date
01/06/2017

Completion date

01/12/2022

Eligibility

Key inclusion criteria
1. Aged 18 – 70 years (men)
2. Aged >18 years and pre-menopausal (women)
3. Right handed
4. Non-smoker
5. Heterosexual orientation
6. Low sexual desire, meeting the DSM-5 criteria for Hypoactive Sexual Desire Disorder
7. Free of current or past physical or psychiatric illness
8. Naive to psychoactive substances, prescribed or illicit, for a minimum of 6 months prior to screening.
9. Normal or corrected-to-normal vision.
10. Absence of a history of sexual aggression/abuse/phobia or psychotherapy/counselling

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
31 men and up to 31 women are required. To allow for drop-out and exclusion rate, up to 35 men and women will be recruited.

Total final enrolment
64

Key exclusion criteria
1. History of any medical, psychological or other condition, or use of any medications, including over-the-counter products, which, in the opinion of the investigators, would either interfere with the study or potentially cause harm to the participant
2. Medical or psychological conditions that would impair their ability to participate reliably in the study or give informed consent
3. Pregnancy and/or breastfeeding
4. Post-menopausal (female)
5. Any implanted material in the body that would preclude magnetic resonance imaging (MRI) for safety reasons
6. Inability to tolerate MRI scanning
7. Without access at home to a telephone, or other factor likely to interfere with ability to participate reliably in the study
8. History of hypersensitivity to any of the components administered

9. Treatment with an investigational drug within the preceding two months
10. Those who have or intend to donate blood or blood products within three months before or following study completion
11. A history of major haematological, renal, thyroid or hepatic abnormalities or significant cardiovascular disease
12. A history of cancer

Date of first enrolment
04/01/2021

Date of final enrolment
01/02/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Imperial College London
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Sponsor information

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Sponsor type
University/education

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ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name

NIHR Imperial Biomedical Research Centre

Alternative Name(s)
NIHR Imperial BRC, Imperial Biomedical Research Centre, BRC

Funding Body Type
Private sector organisation

Funding Body Subtype
Research institutes and centers

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal and presentation at national /international scientific conferences.

Intention to publish date
31/12/2022

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		03/10/2022	27/10/2022	Yes	No
Results article		01/02/2023	06/02/2023	Yes	No
HRA research summary			28/06/2023	No	No