ISRCTN10095215 https://doi.org/10.1186/ISRCTN10095215

Clinical studies to examine the effects of intranasal kisspeptin delivery on reproductive hormones

Submission date
08/03/2022

Recruitment status
No longer recruiting

Registration date
09/03/2022

Overall study status
Completed

Last Edited
28/07/2023

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims:
Kisspeptin is a hormone which acts as the master regulator of reproductive hormone release in humans. Clinical studies demonstrate that intravenous (into a vein) or subcutaneous (under the skin) kisspeptin administration could be used to treat reproductive disorders. A non-invasive delivery route would be preferable to patients and clinicians. To address this, the aim of this study is to find out whether intranasal administration (snorting) of kisspeptin can stimulate reproductive hormone release in healthy volunteers and patients with reproductive disorders.

Who can participate?
Healthy men and women and patients with reproductive disorders, aged 18 – 70 years

What does the study involve?
Participants will attend at least two study visits at least 1 week apart at the Clinical Research Unit (Charing Cross Hospital, London). At one visit kisspeptin will be self-administered using a nasal spray device and at the other visit a placebo (dummy drug) will be used instead. Blood samples will be collected through a cannula (tube) every 15 minutes for 4 hours to measure reproductive hormone release.

What are the possible benefits and risks of participating?
Kisspeptin is a naturally occurring hormone which has been given to over 500 men and women without complications or side effects. The main benefit will be to help develop a future treatment for patients with reproductive disorders.

When is the study starting and how long is it expected to run for?
June 2017 to April 2024

Who is funding the study?
1. Medical Research Council (MRC) (UK)
2. National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Dr Edouard Mills
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
232585

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Protocol version 4, IRAS 232585

Study information

Scientific Title
Investigating the effects of intranasal kisspeptin administration on reproductive hormone secretion

Study objectives
Intranasal kisspeptin administration stimulates reproductive hormone secretion in healthy volunteers and patients with common reproductive disorders.

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, UK; +44 (0)20 7104 8112; riverside.rec@hra.nhs.uk), REC ref: 17/LO/1504

Study design
Randomized placebo-controlled cross-over study

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Reproductive disorders

Interventions
Randomised, placebo-controlled, cross-over study in healthy volunteers (men and women) and patients with common reproductive disorders (including hypothalamic amenorrhoea). Following self-administration of intranasal kisspeptin (dose range 3.2 to 25.6 nmol/kg) or placebo using a nasal spray device, serum reproductive hormones are measured every 15 minutes for 4 hours. Study visits will be at least 1 week apart to ensure washout, with the order of the interventions randomised (using https://www.randomizer.org).

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
Kisspeptin-54

Primary outcome measure
Blood levels of reproductive hormones (kisspeptin, luteinizing hormone, follicle stimulating hormone, testosterone [men] and oestradiol/progesterone [women]) measured using automated chemiluminescent immunoassays at baseline and every 15 minutes for 4 hours

Secondary outcome measures
1. Safety monitoring: heart rate, blood pressure, and the presence of adverse symptoms measured using automated blood pressure monitor every 15 minutes for 4 hours
2. Behavioural parameters of reproductive behaviour assessed using validated psychometric questionnaires (including the Sexual Arousal and Desire Inventory, Positive and Negative Affect Schedule, and State-Trait-Anxiety-Inventory) at baseline and every hour until 4 hours

Overall study start date
01/06/2017

Completion date
01/04/2024

Eligibility

Key inclusion criteria
Healthy volunteers:
1. Aged 18–70 years
2. Non-smokers
3. Free of current or past physical or psychiatric illness
4. Naive to psychoactive substances, prescribed or illicit, for a minimum of 6 months prior to screening.
5. Regular menstrual cycles (women)

For patients with common reproductive disorders:
1. Patients diagnosed in accordance with established guidelines (e.g. Endocrine Society guidelines for hypothalamic amenorrhoea)

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Upper age limit
70 Years

Sex
Both

Target number of participants
A minimum of 12 healthy volunteers and 6 patients with reproductive disorders

Key exclusion criteria
1. History of any medical, psychological or other condition, or use of any medications, including over-the-counter products and hormonal therapies, 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. Without access at home to a telephone, or other factor likely to interfere with ability to participate reliably in the study
5. History of hypersensitivity to any of the components administered
6. Treatment with an investigational drug within the preceding 2 months
7. Those who have or intend to donate blood or blood products within three months before or following study completion
8. A history of major haematological, renal, thyroid or hepatic abnormalities or significant cardiovascular disease
9. A history of cancer

Date of first enrolment
14/01/2020

Date of final enrolment
01/12/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Imperial College London
Clinical Research Unit
Charing Cross Hospital
Fulham Palace Rd
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Sponsor information

Organisation
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Sponsor type
University/education

Website
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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)
NIHR Biomedical Research Centre Bristol, National Institute for Health Research Bristol Biomedical Research Centre, NIHR Bristol BRC, Bristol BRC, Bristol Biomedical Research Centre

Funding Body Type
Private sector organisation

Funding Body Subtype
Research institutes and centers

Location
United Kingdom

Results and Publications

Publication and dissemination plan
1. Presentation at national and international scientific conferences
2. Publication in high-impact medical journals

Intention to publish date
01/08/2024

Individual participant data (IPD) sharing plan
Restrictions apply to the availability of some or all data generated or analyzed during this study to preserve patient confidentiality. The team will on request detail the restrictions and any conditions under which access to some data may be provided. Please contact Prof. Waljit Dhillo (w.dhillo@imperial.ac.uk). The data will only become available once the study has been completed and will be at the discretion of the PI. Most data will not be available due to participant confidentiality.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 5	27/01/2020	09/03/2022	No	Yes
HRA research summary			28/06/2023	No	No