

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

<b>Submission date</b> 08/03/2022	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results <input type="checkbox"/> Individual participant data
<b>Registration date</b> 09/03/2022	<b>Overall study status</b> Completed	
<b>Last Edited</b> 22/08/2025	<b>Condition category</b> Nutritional, Metabolic, Endocrine	

## 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  
imperial.kisspeptin@nhs.net

## Contact information

### Type(s)

Public

### Contact name

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### Type(s)

Principal investigator

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### Integrated Research Application System (IRAS)

232585

### ClinicalTrials.gov (NCT)

Nil known

**Protocol serial number**

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

**Study type(s)**

Treatment

**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(s)**

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

**Key secondary outcome(s)**

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

**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. Naïve 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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Upper age limit**

70 years

**Sex**

All

**Total final enrolment**

34

## **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**

United Kingdom

England

### **Study participating centre**

**Imperial College London**

Clinical Research Unit

Charing Cross Hospital

Fulham Palace Rd

London

United Kingdom

W6 8RF

## **Sponsor information**

### **Organisation**

Imperial College London

ROR

## 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

### 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 Dhillon (w.dhillon@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?
<a href="#">Results article</a>		10/04/2025	22/08/2025	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Participant information sheet</a>	version 5	27/01/2020	09/03/2022	No	Yes
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes