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Clinical studies to examine the effect of kisspeptin in delayed puberty

Submission date	Recruitment status	[X] Prospectively registered
16/03/2023	Recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
27/03/2023	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
18/08/2025	Nutritional, Metabolic, Endocrine	[X] Record updated in last year

Plain English summary of protocol

Background and study aims

Puberty is the time when boys and girls mature into adults, and it usually starts between the ages of 8 and 14. The brain controls puberty, and a small number of children might not start puberty at the same time as most other children. This delay can be caused by a genetic disorder or simply by a normal variation in development. Doctors need to be able to tell the difference between these two groups of children so they can provide the appropriate treatment.

Scientists have found a hormone called 'kisspeptin' that plays an important role in regulating puberty. It works by telling the brain to produce reproductive hormones. Researchers want to study how children with delayed puberty respond to kisspeptin to see if it can help distinguish between those with normal development and those with a genetic disorder. By understanding how kisspeptin affects the body, doctors may be able to create better tests for diagnosing delayed puberty in the future.

Who can participate?

Children with delayed puberty.

What does the study involve?

Participants will attend at least two visits in 2 months, at least 1 week apart at The Children's Clinical Research Facility, St Mary's Hospital, London. At visit one GnRH will be administered intravenously and at the other kisspeptin will be administered. Blood samples will be collected through a cannula (tube) not more than every 15 minutes for up to 4 hours [Visit 1] and not more than every 10 minutes for up to 8 hours [Visit 2] 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 300 men and women without complications or side effects. The main benefit will be to help develop a future diagnostic test/treatment for patients with delayed puberty.

Where is the study run from?

Imperial College London (UK)

When is the study starting and how long is it expected to run for?
December 2017 to November 2027

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Dr Ali Abbara
imperial.kisspeptin@nhs.net

Contact information

Type(s)
Public

Contact name
Dr Ali Abbara

ORCID ID
https://orcid.org/0000-0003-2795-5256

Contact details
6th Floor Commonwealth Building
Imperial College London
Hammersmith Campus
Du Cane Road
London
United Kingdom
W12 0NN
+44 (0)207 594 3487
imperial.kisspeptin@nhs.net

Type(s)
Principal Investigator

Contact name
Prof Waljit S. Dhillo

ORCID ID
https://orcid.org/0000-0001-5950-4316

Contact details
6th Floor Commonwealth Building
Imperial College London
Hammersmith Campus
Du Cane Road
London
United Kingdom

W12 0NN
+44 (0)207 594 3487
imperial.kisspeptin@nhs.net

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
238238

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 238238, CPMS 37187

Study information

Scientific Title
Investigating the physiological hormonal response to kisspeptin in delayed puberty

Study objectives
Children with delayed puberty due to congenital hypogonadotropic hypogonadism (CHH) will have reduced hypothalamic function and thus a minimal response to kisspeptin. By comparison, children with constitutional delay of growth and puberty (CDGP) should have normal hypothalamic function and should therefore respond to kisspeptin.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 02/02/2018, London-West London & GTAC Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 207104 8256; westlondon.rec@hra.nhs.uk), ref: 18/LO/0043

Study design
Interventional non randomized

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)

Diagnostic

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Children with delayed puberty

Interventions
Assessment of hormonal response to kisspeptin and GnRH in delayed puberty.
Visit 1: Following intravenous administration of GnRH (2.5mcg/kg, maximum dose 100mcg) serum reproductive hormones are measured not more than every 15 minutes for up to 4 hours.
Visit 2: Following intravenous administration of kisspeptin-54 (6.4-12.8 nmol/kg) serum reproductive hormones are measured not more than every 10 minutes for up to 8 hours.
Second visit will be performed within 2 months of the first visit.

Intervention Type
Other

Primary outcome measure
Serum luteinising hormone (LH) measured using blood test at each visit not more than every 15 minutes for up to 4 hours.

Secondary outcome measures
1. Serum reproductive hormones (e.g. follicle stimulating hormone [FSH]; testosterone in boys and oestradiol and progesterone in girls) measured using blood test not more than every 10 minutes for up to 8 hours.
2. Safety monitoring: heart rate, blood pressure (measured using automated blood pressure monitor every 15-30 minutes) and the presence of adverse symptoms.

Overall study start date
18/12/2017

Completion date
30/11/2027

Eligibility

Key inclusion criteria
Children with delayed puberty. Girls aged ≥ 13 years old, boys aged ≥ 14 years old.

Participant type(s)
Patient

Age group
Child

Lower age limit
13 Years

Sex
Both

Target number of participants
80 children with delayed puberty

Key exclusion criteria
1. The child is unable or unwilling to give assent
2. Children with untreated anaemia
3. Children with a medical condition that could affect the reproductive axis and prevent evaluation of hormonal response to kisspeptin
4. Children who are currently in a research study or have participated in research in the last three months

Date of first enrolment
04/08/2023

Date of final enrolment
30/09/2027

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Imperial College London
The Children's Clinical Research Facility
St Mary’s Hospital
Praed Street
London
United Kingdom
W2 1NY

Sponsor information

Organisation
Imperial College London

Sponsor details
Hammersmith Campus
Du Cane Road
London

England
United Kingdom
W12 0NN
+44 (0)20 7589 5111
becky.ward@imperial.ac.uk

Sponsor type
University/education

Website
http://imperial.ac.uk

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care 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

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
01/08/2026

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	for parents/legal guardians version 3	31/07/2022	27/03/2023	No	Yes
Participant information sheet	for young people with delayed puberty version 2	31/07/2022	27/03/2023	No	Yes
HRA research summary			28/06/2023	No	No