

Clinical studies to examine the effect of kisspeptin in delayed puberty

Submission date 16/03/2023	Recruitment status Recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 27/03/2023	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 18/08/2025	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> 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
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Contact information

Type(s)

Public

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

238238

Protocol serial number

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

Study type(s)

Diagnostic

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(s)

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

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

13 years

Sex

All

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

United Kingdom

England

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

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

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?
HRA research summary			28/06/2023	No	No
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