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A comparison between the Insulin Tolerance Test (ITT) and the combined growth Hormone Releasing Hormone and Arginine test to determine Growth Hormone (GH) status in cranially irradiated patients.

Submission date	Recruitment status	[_] Prospectively registered
30/09/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/09/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
27/08/2008	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N0063072321

Study information

Scientific Title

Study objectives
We aim to study the pattern of growth hormone response to a combination of GHRH (growth hormone releasing hormone) plus Arginine in adults with radiation induced growth hormone deficiency, to find out whether this stimulation test can successfully replace the Insulin Tolerance Test (ITT) for the diagnosis of radiation-induced growth hormone.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Nutritional, Metabolic, Endocrine: Growth hormone deficiency

Interventions
Patients will be reviewed in Endocrine Clinic. Those who fulfil the inclusion criteria will be invited to participate. An information sheet will provide full details of the study and what is involved. It is established practice that patients sign an informed consent before undergoing GH tests. Patients will undergo the ITT and GHRH+ARG. Stimulation tests in random order, at least three days apart. After overnight fasting, the patient will be admitted to the endocrine unit at 08:30h. A cannula will be inserted into a forearm vein and kept patent by normal saline. For the ITT, a bolus of 0.1u/kgregular insulin (actrapid) will be given intravenously and the blood glucose level measured (by glucometer) every 15 min. The patient will not be left unattended until the test is finished and the blood glucose level has returned to normal.
For the GHRH+Arginine test, a bolus of 1ug/kg GHRH24 will be infused over 30 min, from 0 to 30 min. Blood samples will be taken every 15 min from -15 to 120 min. They will be assayed for GH, IGF-I, IGFBP3 and Acid Labile sub-unit (ALS).

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)

combination of GHRH (growth hormone releasing hormone) plus Arginine

Primary outcome(s)
Primary end point: growth hormone response to different provocative tests.

Key secondary outcome(s))
Not provided at time of registration

Completion date
31/12/2008

Eligibility

Key inclusion criteria
Not provided at time of registration

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Not Specified

Key exclusion criteria
1. Patients with pituitary tumours or previous surgery in the hypothalamic-pituitary field (non radiation-induced damage)
2. Patients with active or uncured malignancy
3. Patients who are suffering from any condition or disease or taking any medication that might affect the function of the hypothalamic-pituitary axis or interfere with the interpretation of the tests
4. Failure to sign an informed consent

Date of first enrolment
26/05/2000

Date of final enrolment
31/12/2008

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Endocrinology
Manchester
United Kingdom
M20 4BX

Sponsor information

Organisation
Department of Health

Funder(s)

Funder type
Government

Funder Name
Christie Hospital NHS Trust, Christie Endocrinology Department Research Fund (UK), NHS R&D Support Funding

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2003		Yes	No