

GHD Reversal Trial: Randomisation Form

This paper randomisation form should be completed once written informed consent has been given. Once fully complete, please follow the instructions in Section 6 in order to randomise the patient.

Section 1 - Screening

Has the entry for this patient on the GHD Reversal Trial Screening Log been completed? *Please tick one* No Yes

Section 2 - Participant Details

Site name Patient DOB *e.g. 31-JAN-2017* - -

Sex Female Male

Section 3 - Eligibility Checklist

Inclusion criteria checklist

One of the two following diagnostic criteria must be ticked as **Yes** for the patient to be eligible.

Does the patient have idiopathic, isolated growth hormone deficiency (I-GHD), defined as having two abnormal GH stimulation tests (peak GH <6.7µg/L) irrespective of sex-hormone priming for GH stimulation tests? *Please tick one* No Yes

OR Does the patient have idiopathic, isolated growth hormone deficiency (I-GHD), defined as one abnormal stimulation test with serum IGF-1 below, or in the lower tertile of, normal range for sex and age irrespective of sex-hormone priming for GH stimulation tests? *Please tick one* No Yes

If the patient has met one of the above diagnostic criteria, **please proceed with the eligibility checklist.**

Has the patient undergone an MRI brain scan? *Please tick one* No Yes

If yes, were the results of the MRI brain scan normal (including small anterior pituitary)? *Please tick one* No Yes

Is the patient between the ages of 8-15 years (inclusive) if female, or between the ages of 9-17 years (inclusive) if male? *Please tick one* No Yes

Is the patient in established puberty? *Please tick one* No Yes

If female, please select appropriate Tanner stage *Please tick one* B2 B3 Other

If male, please provide testicular volume of the largest testicle (ml) *Please tick one. Where testicular volume falls between bead sizes, please report larger measurement.* 6 8 10 12 Other

Did the patient discontinue growth hormone therapy at least 4 weeks prior to re-testing? *Please tick one* No Yes

Following discontinuation of growth hormone therapy, has the patient undergone a growth hormone stimulation test (using glucagon, arginine or insulin tolerance test)? *Please tick one* No Yes

If yes, was the peak growth hormone >=6.7µg/L? *Please tick one* No Yes

Following discontinuation of growth hormone therapy, has the patient undergone a serum Insulin-like growth factor 1 (IGF-1) test? *Please tick one* No Yes

If yes, was the serum IGF-1 within the normal reference range for sex and age? *Please tick one* No Yes

Has the patient remained off growth hormone therapy from the time of re-test until randomisation? *Please tick one* No Yes

Is the patient able to tolerate the administration of growth hormone therapy? *Please tick one* No Yes

Is the patient able to comply with the trial schedule and follow up? *Please tick one* No Yes

Please note: if any of the shaded boxes above are ticked then the patient is **ineligible** to take part in the GHD Reversal Trial.

Section 4 - Exclusion Criteria Checklist

Does the patient have multiple pituitary hormone deficiency (hypopituitarism) with or without additional pituitary hormone supplementation?

Please tick one

No Yes

Does the patient have any known genetic causes of I-GHD? Please tick one

No Yes

Does the patient have organic GHD (mid-brain tumours, congenital mid-brain malformations, septo-optic dysplasia; radiotherapy to the total body or brain)? Please tick one

No Yes

Does the patient have an ectopic posterior pituitary? Please tick one

No Yes

Does the patient have any other indications for receiving growth hormone therapy? Please tick one

No Yes

Has the patient received growth hormone therapy since commencing the (minimum) 4 week GH discontinuation period? Please tick one

No Yes

Did the patient receive prednisolone or dexamethasone at any time during the (minimum) 4 week GH discontinuation period prior to re-test?

Please tick one

No Yes

Does the patient have a documented history of persistent non-compliance with prescribed medication regimens? Please tick one

No Yes

Is the patient pregnant or lactating? Please tick one

No Yes

Does the patient have a malignancy? Please tick one

No Yes

Is the patient currently participating in another trial of an investigational medicinal product? Please tick one

No Yes

Please note: if any of the shaded boxes above are ticked then the patient is **ineligible** to take part in the GHD Reversal Trial.

Section 5 - Consent

Has written informed consent been given by parent or guardian, or patient if aged 16-18yrs? Please tick one

No Yes

If yes, Consent Form version number

Participant Information Sheet version number

Has written assent been obtained from the patient (if age appropriate)? Please tick one

No Yes

If yes, Assent Form version number

Please note: if any of the shaded boxes above are ticked then the patient is **ineligible** to take part in the GHD Reversal Trial.

Section 6 - Investigator Sign Off

I confirm that I have checked the eligibility criteria for the GHD Reversal Trial and that the patient meets all of the inclusion criteria and none of the exclusion criteria as detailed above. I have documented this information in the patient medical records.

Investigator name <input type="text"/>	Signature <input type="text"/>	Date e.g. 31-JAN-2017 D D - M M M - Y Y Y Y
PI Name <input type="text"/>	Signature <input type="text"/>	Date: e.g. 31-JAN-2017 D D - M M M - Y Y Y Y

Section 7 - Randomisation Allocation

When the above sections of this form are complete, the patient can be enrolled into the GHD Reversal Trial. **To enrol a participant, please log on at: <https://ghd.bctu.bham.ac.uk/> and follow the onscreen instructions. Alternatively, please call the BCTU Trial Manager directly on +44 121 415 9131, Monday to Friday 09:00 to 17:00 UK time (excluding bank holidays and University of Birmingham closed days).**

Trial Number <input type="text"/>	Randomisation Date e.g. 31-JAN-2017 D D - M M M - Y Y Y Y
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Trial Allocation Please tick one Control- continue growth hormone Experimental- withdraw growth hormone

Original paper randomisation form to be kept in the GHD Reversal Trial site file, one copy kept with patient's notes and one copy to be posted to: **Birmingham Clinical Trials Unit (BCTU), Institute of Applied Health Research, College of Medical and Dental Sciences, Public Health Building, University of Birmingham, B15 2TT, United Kingdom**

Thank you for randomising to the GHD Reversal Trial.