The GHD Reversal Trial:

Effect on final height of discontinuation vs continuation of growth hormone treatment in pubertal children with isolated growth hormone deficiency

Trial Registration: ISRCTN12552768

Basic Results Summary

Date: December 2025

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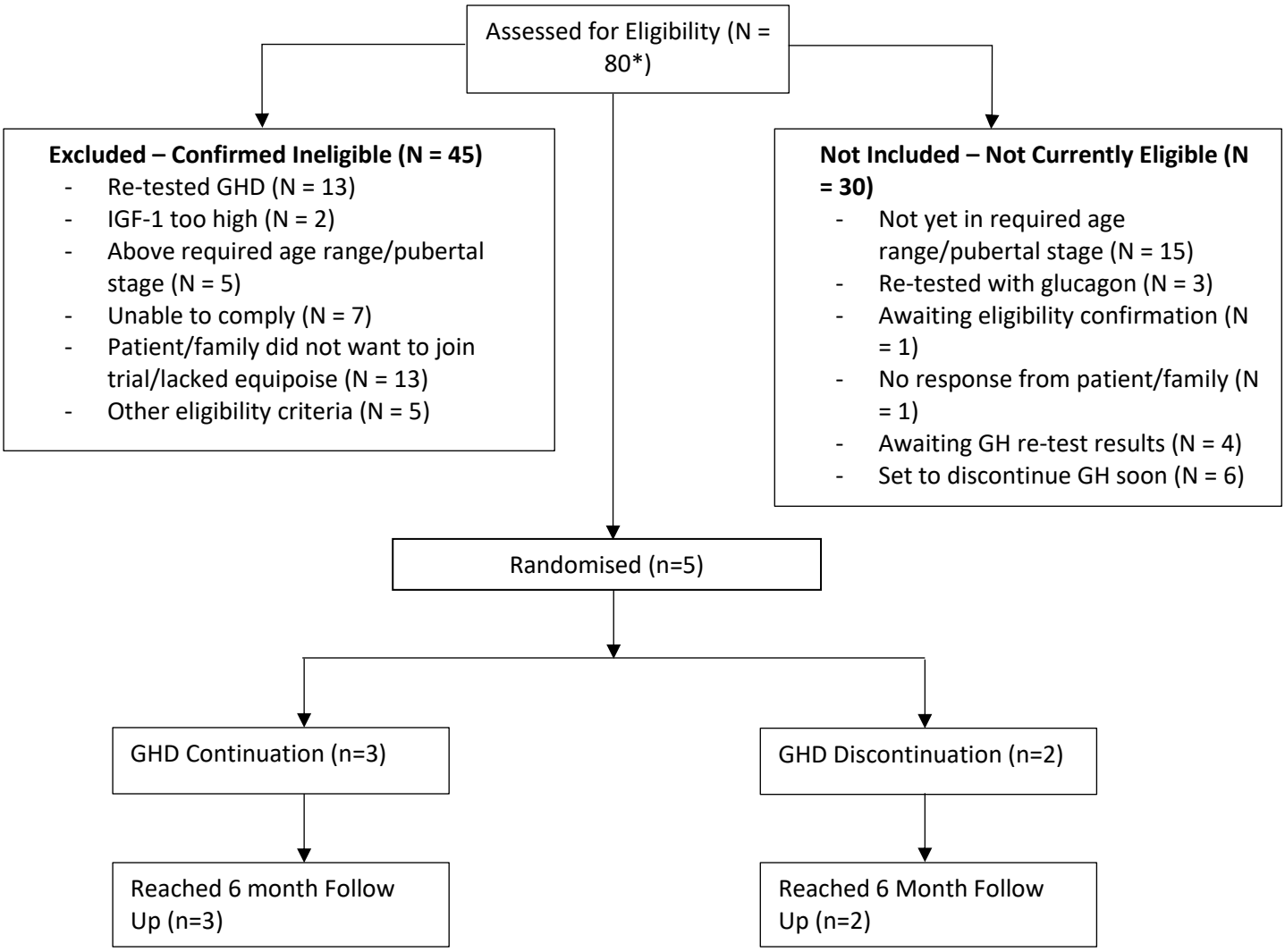
1. Participant Flow

Figure 1 details the flow of participants through the trial.

Figure 1: Consort Diagram



*This does not include pre-screening data. The screening log was designed to capture patients who had discontinued GH medication (as this was standard care for sites in the trial) for an early puberty GH re-test.

Including data provided by Manchester and Barts regarding pre-screening, total number assessed was approximately 300, however most of these (approx. 200) were not within our target patient population.

Further details on participant drop-out is given in Table 1 below.

Table 1: Participant trial exit (attrition) by group

	GH- (n=2)	GH+ (n=3)
Number withdrawn	0	0
Number lost to follow-up	0	0
Number of deaths	0	0

Data for participants who withdrew, were lost to follow-up or died are included in any analyses up to the point of withdrawal, lost to follow-up or death.

2. Baseline Characteristics

The characteristics of the participants in the trial by group are shown in Table 2. The minimisation variables used in the randomisation are listed first.

Table 2: Participant baseline characteristics

Minimisation variables		**n=5**
Gender	Male	4 (80%)
	Female	1 (20%)
Puberty Stage	Puberty Stage 2 (6-<9ml testicular volume / Tanner Stage B2)	1 (20%)
	Puberty Stage 3 (9-12ml testicular volume / Tanner Stage B3)	4 (80%)
Centre	Queen's Medical Centre (Nottingham University Hospitals NHS Trust)	1 (20%)
	Royal London Hospital (Barts Health NHS Trust)	1 (20%)
	LKH-Univ. Klinikum Graz	1 (20%)
	UniversitÃ¤tsklinikum Innsbruck	1 (20%)
	Great Ormond Street Hospital for Children NHS Foundation Trust	1 (20%)
Participant Baseline Characteristics		
Age (years)	Mean (SD)	13.4 (0.9)
	Min - max	12 - 14
Baseline Height (cm)	Mean (SD)	153.7 (3.6)
	Min - max	148.8 – 159.0
Target Adult Height (cm)[1]	Mean (SD)	175.1 (8.6)
	Min - max	164.0 – 183.0
Weight (Kg)	Mean (SD)	41.5 (2.1)
	Min - max	39.6 – 45.0
Tanner stage (P)	Stage 2	2 (40%)
	Stage 3	3 (60%)
	Stage 4	0
	Stage 5	0

[1]Calculated using Tanner's formula

Data are either mean (SD) or number (%)

Details of the GH simulation test and IGF-1 concentration assay at diagnosis and retest are given in Table 3.

Table 3: Diagnostic testing details

		n=5
GH stimulation tests at diagnosis		
Test 1		
Peak GH (µg/L)	Mean (SD)	5.3 (1.3)
	Min - max	4.3 – 7.6
Test used	Insulin tolerance test	0
	Arginine	3 (60%)
	Glucagon	2 (40%)
	Other	0

		n=5
Test sex steroid primed	Yes	0
	No	4 (100%)
	Missing	1
Diagnostic peak GH cut off used at diagnosis (µg/L)	Mean (SD)	6.6 (1.0)
	Min - max	5.1 – 8.0
Test 2 – *Limited Data means we are unable to report this*		
Peak GH (µg/L)	Mean (SD)	*NA*
	Min - max	*NA*
Test used	Insulin tolerance test	*NA*
	Arginine	*NA*
	Glucagon	*NA*
	Other	*NA*
	Missing	*NA*
Test sex steroid primed	Yes	*NA*
	No	*NA*
	Missing	*NA*
Diagnostic peak GH cut off used at diagnosis (µg/L)	Mean (SD)	*NA*
	Min - max	*NA*
GH re-test		
Peak GH (µg/L)	Mean (SD)	9.8 (2.1)
	Min - max	7.6 – 12.8
Test used	Insulin tolerance test	1 (20%)
	Arginine	3 (60%)
	Glucagon	1 (20%)
Test sex steroid primed	Yes	0
	No	5 (100%)
Serum IGF-1 at diagnosis		
Serum IGF-1 concentration (ng/mL)	Mean (SD)	81.6 (21.8)
	Min - max	59.0 – 105.8
Assay used	IDS iSYS	1 (25%)
	Immulite 2000 Family	0
	Roche Elecsys	1 (25%)
	Siemens Immulite	1 (25%)
	Diasorin Liaison XL	1 (25%)
	Other	0
	Missing	1
Serum IGF-1 at re-test		
Serum IGF-1 concentration (ng/mL)	Mean (SD)	259.2 (120.6)
	Min - max	173.0 – 443.7
Assay used	IDS iSYS	2 (50%)
	Immulite 2000 Family	0
	Roche Elecsys	1 (25%)
	Siemens Immulite	0
	Diasorin Liaison XL	1 (25%)
	Other	0
	Missing	1

3. Outcome Measures

Note from trial statisticians:

Table 4: Deviations for the SAP

Section of report not following SAP	Reason
Outcomes and Analysis	Due to trial's early closure, only baseline and key summary data reported and no analyses undertaken

Table 5 gives information on overall adherence to randomised treatment allocation. For the GH+ arm, adherence was monitored using self-reported adherence data, defined as ≥85% reported adherence at every follow-up visit. For the GH- group, any evidence of GH use post-randomisation would have resulted in the participant being considered as non-adherent. GH use was asked at each follow-up visit.

Table 5: Treatment adherence by group

Time-point		GH- n=2	GH+ n=3
6 months	Number compliant with randomised allocation	2 (100%)	3 (100%)
	Number non-compliant with randomised allocation	0	0

4. Adverse Events

There were no adverse events associated with this study. There were no protocol deviations reported in the GHD Reversal trial.