Trials

CORRECTION

Open Access

Correction: Effects of half-dose spiomet treatment in girls with early puberty and accelerated bone maturation: a multicenter, randomized, placebo-controlled study protocol

Judit Bassols[1†], Francis de Zegher[2†], Marta Diaz[3,4], Gemma Carreras-Badosa[5], Cristina Garcia-Beltran[3,4], Elsa Puerto-Carranza[6], Cora Oliver-Vila[5], Paula Casano[3,4], Celine Alicia Franco[3], Rita Malpique[3,4], Abel Lopez-Bermejo[5,6,7*†] and Lourdes Ibanez[3,4*†]

Correction: Trials 24, 56 (2023)
https://doi.org/10.1186/s13063-022-07050-w

After publication of the article [1] the authors noticed several errors related to the inclusion and exclusion criteria. The clinical trial registration has been updated and the ethical committee has reviewed the changes.

Incorrect	Correct
Inclusion criteria 1) Age at study start 8.0–9.3 years; 2) BW for gestational age in lower tertile (− 1.96 < Z-score < − 0.44); 3) BMI for CA in upper tertile (+ 0.44 < Z-score < + 1.96) [2]; 4) Early progressive puberty [bilateral breast development (Tanner stage 2)] starting between 7.7 and 9.0 years, with a minimum of 4 months of progression) [3, 4]; 5) White ethnicity; 6) Full-term pregnancy: 37 ≤ gestational age < 42 weeks; 7) Height at 1st visit: 3rd percentile ≤ height ≤ 97th percentile; and 8) Written informed consent of parents or legal representative.	*Inclusion criteria* 1) Age at study start 8.0–9.3 years; 2) BW for gestational age in lower tertile (-2.5 < Z-score < 0); 3) BMI for CA in upper tertile (0 < Z-score < + 2.5) (2); 4) Early progressive puberty [bilateral breast development (Tanner stage 2)] starting between 7.7-9.3 years, with a minimum of 2 months of progression) (3,4); 5) White ethnicity; 6) Full-term or late preterm pregnancy: 34 ≤ gestational age < 42 weeks; 7) Height at 1st visit: 3rd percentile ≤ height ≤ 97th percentile (adjusted by pubertal stage); 8) Written informed consent of parents or legal representative.

†Judit Bassols and Francis de Zegher are joint first authors.

†Abel Lopez-Bermejo and Lourdes Ibanez are joint final authors and correspondence.

The original article can be found online at https://doi.org/10.1186/s13063-022-07050-w.

*Correspondence:
Abel Lopez-Bermejo
alopezbermejo@idibgi.org
Lourdes Ibanez
lourdes.ibanez@sjd.es
[1] Maternal-Fetal Metabolic Research Group, Girona Biomedical Research Institute (IDIBGI), Girona, Spain
[2] Leuven Research & Development, University of Leuven, Leuven, Belgium
[3] Endocrinology Department, Pediatric Research Institute Sant Joan de Deu, University of Barcelona, Barcelona, Spain
[4] Centro de Investigacion Biomedica en Red de Diabetes Y Enfermedades Metabolicas Asociadas, Instituto de Salud Carlos III, Madrid, Spain
[5] Pediatric Endocrinology Research Group, Girona Biomedical Research Institute (IDIBGI), Girona, Spain
[6] Pediatrics, Dr. Josep Trueta Hospital, Girona, Spain
[7] Department of Medical Sciences, University of Girona, Girona, Spain

Incorrect	Correct
Exclusion criteria 1) Excessive delay or advance of bone age (more than 2 years for chronological age); 2) Tanner stage of breast development greater than 2; 3) Twin pregnancy; 4) Obesity at 1st visit (BMI Z-score above + 1.96 for chronological age); 5) Evidence for a pathological cause of the rapid maturation (i.e., congenital adrenal hyperplasia due to 21-hydroxylase deficiency); 6) Known genetic abnormality or chronic conditions, including cardiovascular, neurological, immunological, metabolic, renal, endocrine, digestive, respiratory or oncological diseases; 7) Chronic use of medications, among others: anticoagulants, anti-inflammatories, oral hypoglycemic agents, antiandrogens, estrogens, progestins, glucocorticoids, digoxin. Only the use of paracetamol before or during the course of the study will be accepted; 8) Acute infections or intake of antibiotics or anti-inflammatory medication in the last 14 days; 9) Previous history of hypersensitivity to any of the drugs used in the clinical trial, or to its excipients; and 10) Any disease that, in the opinion of the investigator, compromises the inclusion of the subject in the clinical trial.	*Exclusion criteria* 1) Excessive delay or advance of bone age (more than 2 years for chronological age); 2) Tanner stage of breast development greater than 2; 3) Twin pregnancy; 4) Obesity at 1st visit (BMI Z-score above + 2.5 for chronological age); 5) Evidence for a pathological cause of the rapid maturation (i.e., congenital adrenal hyperplasia due to 21-hydroxylase deficiency); 6) Known genetic abnormality or chronic conditions, including cardiovascular, neurological, immunological, metabolic, renal, endocrine, digestive, respiratory or oncological diseases; 7) Chronic use of medications, among others: anticoagulants, anti-inflammatories, oral hypoglycemic agents, antiandrogens, oestrogens, progestins, glucocorticoids, digoxin. Only the use of paracetamol before or during the course of the study will be accepted; 8) Acute infections or intake of antibiotics or anti-inflammatory medication in the last 14 days; 9) Previous history of hypersensitivity to any of the drugs used in the clinical trial, or to its excipients; 10) Any disease that, in the opinion of the investigator, compromises the inclusion of the subject in the clinical trial.

Published online: 03 October 2023

Reference

1. Bassols J, et al. Effects of half-dose spiomet treatment in girls with early puberty and accelerated bone maturation: a multicenter, randomized, placebo-controlled study protocol. Trials. 2023;24:56. https://doi.org/10.1186/s13063-022-07050-w.