

ICMJE DISCLOSURE FORM

Date: 12/14/2021

Your Name: Chris Severyn, MD, PhD

Manuscript Title: Randomized controlled trial of gut decontamination in pediatric patients undergoing allogeneic hematopoietic cell transplantation

Manuscript Number (if known): 154344-JCI-CMED-1

In the interest of transparency, we ask you to disclose all relationships/activities/interests listed below that are related to the content of your manuscript. "Related" means any relation with for-profit or not-for-profit third parties whose interests may be affected by the content of the manuscript. Disclosure represents a commitment to transparency and does not necessarily indicate a bias. If you are in doubt about whether to list a relationship/activity/interest, it is preferable that you do so.

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ICMJE DISCLOSURE FORM

Date: 12/14/2021

Your Name: Sandra Kong

Manuscript Title: Randomized controlled trial of gut decontamination in pediatric patients undergoing allogeneic hematopoietic cell transplantation

Manuscript Number (if known): 154344-JCI-CMED-1

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Date: Click or tap to enter a date. 12/14/21

Your Name: Click or tap here to enter text. Angel Moreno

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Manuscript Number (if known): 154344-JCI-CMED-1

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Your Name: Michelle M. Li

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ICMJE DISCLOSURE FORM

Date: 12/15/2021

Your Name: Nan Chen

Manuscript Title: Randomized controlled trial of gut decontamination in pediatric patients undergoing allogeneic hematopoietic cell transplantation

Manuscript Number (if known): 154344-JCI-CMED-1

In the interest of transparency, we ask you to disclose all relationships/activities/interests listed below that are related to the content of your manuscript. "Related" means any relation with for-profit or not-for-profit third parties whose interests may be affected by the content of the manuscript. Disclosure represents a commitment to transparency and does not necessarily indicate a bias. If you are in doubt about whether to list a relationship/activity/interest, it is preferable that you do so.

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ICMJE DISCLOSURE FORM

Date: 12/15/2021

Your Name: Christine N. Duncan, MD

Manuscript Title: Randomized controlled trial of gut decontamination in pediatric patients undergoing allogeneic hematopoietic cell transplantation

Manuscript Number (if known): 154344-JCI-CMED-1

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ICMJE DISCLOSURE FORM

Date: 12/14/2021

Your Name: Leslie Lehmann, MD.

Manuscript Title: Randomized controlled trial of gut decontamination in pediatric patients undergoing allogeneic hematopoietic cell transplantation

Manuscript Number (if known): 154344-JCI-CMED-1

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ICMJE DISCLOSURE FORM

Date: 12/15/2021

Your Name: Steven Margossian

Manuscript Title: Randomized controlled trial of gut decontamination in pediatric patients undergoing allogeneic hematopoietic cell transplantation

Manuscript Number (if known): 154344-JCI-CMED-1

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ICMJE DISCLOSURE FORM

Date: 12/14/2021

Your Name: Shan Sun

Manuscript Title: Randomized controlled trial of gut decontamination in pediatric patients undergoing allogeneic hematopoietic cell transplantation

Manuscript Number (if known): 154344-JCI-CMED-1

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ICMJE DISCLOSURE FORM

Date: 12/14/2021

Your Name: Tessa Andermann, MD

Manuscript Title: Randomized controlled trial of gut decontamination in pediatric patients undergoing allogeneic hematopoietic cell transplantation

Manuscript Number (if known): 154344-JCI-CMED-1

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ICMJE DISCLOSURE FORM

Date: 12/15/2021

Your Name: Sophie Silverstein

Manuscript Title: Randomized controlled trial of gut decontamination in pediatric patients undergoing allogeneic hematopoietic cell transplantation

Manuscript Number (if known): 154344-JCI-CMED-1

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ICMJE DISCLOSURE FORM

Date: 12/15/2021

Your Name: Soomin Kim

Manuscript Title: Randomized controlled trial of gut decontamination in pediatric patients undergoing allogeneic hematopoietic cell transplantation

Manuscript Number (if known): 154344-JCI-CMED-1

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ICMJE DISCLOSURE FORM

Date: 12/14/2021

Your Name: Olga Birbrayer

Manuscript Title: Randomized controlled trial of gut decontamination in pediatric patients undergoing allogeneic hematopoietic cell transplantation

Manuscript Number (if known): 154344-JCI-CMED-1

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ICMJE DISCLOSURE FORM

Date: 12/14/2021

Your Name: Niaz Banaei

Manuscript Title: Randomized controlled trial of gut decontamination in pediatric patients undergoing allogeneic hematopoietic cell transplantation

Manuscript Number (if known): 154344-JCI-CMED-1

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ICMJE DISCLOSURE FORM

Date: 12/14/2021

Your Name: Jerome Ritz

Manuscript Title: Randomized controlled trial of gut decontamination in pediatric patients undergoing allogeneic hematopoietic cell transplantation

Manuscript Number (if known): 154344-JCI-CMED-1

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11	Stock or stock options	<input checked="" type="checkbox"/> None <table border="1" data-bbox="383 258 1518 359"> <tr><td></td><td></td></tr> <tr><td></td><td></td></tr> <tr><td></td><td></td></tr> </table>							
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	<input checked="" type="checkbox"/> None <table border="1" data-bbox="383 476 1518 577"> <tr><td></td><td></td></tr> <tr><td></td><td></td></tr> <tr><td></td><td></td></tr> </table>							
13	Other financial or non-financial interests	<input checked="" type="checkbox"/> None <table border="1" data-bbox="383 690 1518 791"> <tr><td></td><td></td></tr> <tr><td></td><td></td></tr> <tr><td></td><td></td></tr> </table>							
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ICMJE DISCLOSURE FORM

Date: 12/14/2021

Your Name: Anthony Fodor

Manuscript Title: Randomized controlled trial of gut decontamination in pediatric patients undergoing allogeneic hematopoietic cell transplantation

Manuscript Number (if known): 154344-JCI-CMED-1

In the interest of transparency, we ask you to disclose all relationships/activities/interests listed below that are related to the content of your manuscript. "Related" means any relation with for-profit or not-for-profit third parties whose interests may be affected by the content of the manuscript. Disclosure represents a commitment to transparency and does not necessarily indicate a bias. If you are in doubt about whether to list a relationship/activity/interest, it is preferable that you do so.

The author's relationships/activities/interests should be defined broadly. For example, if your manuscript pertains to the epidemiology of hypertension, you should declare all relationships with manufacturers of antihypertensive medication, even if that medication is not mentioned in the manuscript.

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ICMJE DISCLOSURE FORM

Date: 12/14/2021

Your Name: Wendy B. London

Manuscript Title: Randomized controlled trial of gut decontamination in pediatric patients undergoing allogeneic hematopoietic cell transplantation

Manuscript Number (if known): 154344-JCI-CMED-1

In the interest of transparency, we ask you to disclose all relationships/activities/interests listed below that are related to the content of your manuscript. "Related" means any relation with for-profit or not-for-profit third parties whose interests may be affected by the content of the manuscript. Disclosure represents a commitment to transparency and does not necessarily indicate a bias. If you are in doubt about whether to list a relationship/activity/interest, it is preferable that you do so.

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ICMJE DISCLOSURE FORM

Date: 12/14/2021

Your Name: Ami S. Bhatt

Manuscript Title: Randomized controlled trial of gut decontamination in pediatric patients undergoing allogeneic hematopoietic cell transplantation

Manuscript Number (if known): 154344-JCI-CMED-1

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ICMJE DISCLOSURE FORM

Date: 12/14/2021

Your Name: Jennifer Whangbo

Manuscript Title: Randomized controlled trial of gut decontamination in pediatric patients undergoing allogeneic hematopoietic cell transplantation

Manuscript Number (if known): 154344-JCI-CMED-1

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		Vor Biopharma	Stock options
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Checklist for submitting a revised Clinical Medicine manuscript

In addition to addressing the items noted in the decision letter regarding your manuscript, ensure that your revised manuscript adheres to the guidelines below. For full submission details, [visit the JCI Insight website](#).

Required files

Manuscript

- PDF of a clean version of the entire manuscript, including Figures, Figure legends, and Tables
- PDF of a marked-up version of the entire manuscript showing revisions and prefaced by a point-by-point response to reviewer comments
- Word or RTF file of all text of the submission, including Figure legends, Tables, Table legends, and References (without Figures, images, or point-by-point responses)
- Single PDF file of completed ICMJE uniform disclosure forms from all authors
- For clinical trials, PDF of the appropriate reporting checklist (CONSORT, STROBE, etc.)

Figures

- Publication-quality figures in TIFF format. See detailed [instructions for figure preparation](#).
- Recommended: Graphical abstract ([details available here](#))

Supplemental material

- Single file containing supplemental material, figures, and modest-sized tables, as:
 - (if applicable) a PDF highlighting reviewer-requested changes
 - a clean, publication-quality PDF
- Upload any supplemental videos and/or large Excel files separately

Gels

- APDF, PPT, or PPTX file (distinct from any other supplemental material) that shows the entire unedited gel
- Clearly indicate which bands were used for the figures

Formatting

- Maximum 12,000 words (all text inclusive of title page, full text, references, figure legends, and tables)
- Double-spacing throughout, including references and tables; figure legends may be single spaced if necessary to keep a figure and its legend on the same page
- All pages numbered
- Each section begins on a new page

Abbreviations and acronyms

- [Standard JCI Insight abbreviations and acronyms](#) used without definition
- All other abbreviations and acronyms spelled out at first use in the Abstract and again at first use in the main text (with the abbreviated form appearing in parentheses), and used without definition thereafter

Gene and protein names and symbols

- Conform to official [NCBI Gene Nomenclature](#)
- Presented according to [JCI Insight Gene nomenclature and style](#)

Italicization

- Generally reserved for gene symbols, genotypes, and species names
- Terms such as *in vivo*, *in vitro*, etc., are not italicized

Unpublished data, manuscripts in preparation or under review, and personal communications

- Cited parenthetically in the text, not as numbered references; e.g., "(Jane L. Doe, UCLA, Los Angeles, California, USA, unpublished observations)"
- Written permission to cite unpublished observations of someone outside the author's research team (an email is sufficient) is submitted

Reference citations

- Appear in parentheses preceded by a space, e.g., "as described previously (1, 2)"; "several research groups (4–10) have found"
- No superscript, bold, italics, etc.

Figure and table callouts

- Figures and tables called out in numerical order
- "Figure", "Table", "Supplemental Figure", "Supplemental Table", etc., spelled out
- Callouts in parentheses (no boldface or italics) unless grammatically part of the sentence: "the levels increased (Figure 5A)"; "data shown in Table 2"
- Parts called out as follows: "Figure 1A", "Figure 2, A and B", "Figure 3, B–D"

Manuscript preparation and required reporting

Title page

Manuscript title

- Clear, concise, and limited to 15 words, including conjunctions
- Refers to the relevant disease or disease model studied
- No subtitles, colons, periods, or nonstandard abbreviations

Authors and affiliations

- Author names provided in full (for example, "Benita J. Sjögren") and in the appropriate order
- No titles, honorifics, degrees, or certifications
- Author affiliations correspond to the period when the work was performed
- For authors whose affiliation has changed since completion of the work, specify the present affiliation and location below the numbered list
- Affiliation footnotes assigned consecutively using superscripted numbers (1, 2, 3, etc.)
- Affiliations include departments, institutions, city, state (if applicable), and country (but not mailing addresses or zip/regional codes)
- Corresponding author's complete name, address, telephone number (including country code if applicable), and email address
- Consortium/study groups shown as authors (e.g., CARDIoGRAM Consortium)

- Unless the members of the group appear as authors, each individual member and their affiliation are listed in the supplemental material, under the heading Supplemental Acknowledgments
- The following sentence appears in Acknowledgments: "See Supplemental Acknowledgments for details on [name of consortium]."

Conflict-of-interest statement

- A statement consistent with the Journal's conflict-of-interest policy is included; if no author has a conflict, state the following: "The authors have declared that no conflict of interest exists."
- If patents are involved, the patent or patent application number(s) are provided, and the names of the associated authors specified

Abstract

Structured format with the sections Background, Methods, Results, Conclusion, Trial registration, Funding

Maximum 250 words

No references

All nonstandard abbreviations defined at first use

Main text (presented in the following order)

Introduction

Results

Discussion

Methods

Demographic reporting

Reporting on race and ethnicity adheres to [NIH guidelines](#) or other applicable authoritative standards

Descriptors for any demographic identities are clear, unbiased, and up-to-date

Data for any demographic variable are inclusive; if any information is unavailable or incomplete, an explanation is provided

Specify whether the participants or investigators made the classifications; and whether the options were defined by the investigators or participants

Complete manufacturer name (omit location) provided for each proprietary item used

For animal models, precise genotype, strain, number of backcrosses, sex, age, and source are specified

Description of all antibodies used, including the source and catalog/clone number for commercial antibodies or (reference to) a description of the generation of custom antibodies

Source of all cell lines used is indicated

Data sets for gene expression microarrays, SNP arrays, and high-throughput sequencing studies are deposited in a public repository, and accession number(s) provided in Methods the main text (for publication, data must be publicly available)

Statistics

Section appears near the end of Methods (before “Study approval”)

The *P* value used to determine significance is specified; e.g., “A *P* value less than 0.05 was considered significant.”

Analysis appropriately corrects for multiple comparisons (more than 2 groups) and for repeated measures (multiple measurements within subjects)

If samples were excluded, a statement describes inclusion/exclusion criteria

Study approval

Stand-alone paragraph at the end of Methods

Declaration of approval of human and/or animal studies, specifying the name and location of the appropriate institutional review board(s)

For human studies, a statement indicating receipt of written informed consent from participants and/or their parents/guardians

For use of photographs of patients, a separate statement of written informed consent

Author contributions

Contribution of each author (identified by initials) is specified

Grammatically complete sentences

For manuscripts with 2 or more co-first authors, the method used to assign authorship order among these authors is stated

Acknowledgments

States sources of support in the form of grants, equipment, or drugs

Grant numbers provided as applicable

Other appropriate acknowledgments, such as of colleagues for advice

References

Styled according to [Journal reference instructions](#)

Figure legends

Maximum 300 words

Each begins with stand-alone title, irrespective of the individual parts

Figure parts called out in boldface: **(A)**, **(B–D)**, **(C and E)**

Symbols and abbreviations introduced in figures are defined

In each figure legend where appropriate, the statistical test(s) used is described

Variance around the mean and statistical analysis not provided for figures representing fewer than 3 independent samples

For figure panels representing multiple experiments, exact number of samples (*n*) is reported

For representative experiments, the number of times the experiment was conducted is reported

For histological panels and insets, scale bars are defined or total original magnification is specified in the figure legends

Figures

Prepared according to [Journal figure instructions](#)

For clinical trials, the appropriate flow diagram appears as a figure

Parts labeled with capital letters: A, B, C, etc., with no designated subparts

Graphs of quantitative data presented as either dot plots, with average and appropriate error bars indicated; or box-and-whisker plots, with values defined in the legend (bounds of the boxes, lines within the boxes, whiskers, and any outlying values); dynamite plunger plots are not permitted

If lanes in a gel or blot image are spliced together into a composite image, the lanes are separated with a thin vertical line (black on gray background; white on black background); a note in the legend states that the lanes were run on the same gel but were noncontiguous

Tables

Prepared in Word table format (not pasted in from another application)

Self-contained and self-explanatory

Each table fits on a single page and is presented on its own page

Preceded by brief titles

Callouts to footnotes (designated with superscript capital letters) assigned alphabetically row by row

No subparts or subsections (for example, Table 1A and Table 1B)

Column headings in tables apply to all values throughout the column; a new row of column headings may not be introduced within a table

See “Methods” above for reporting on demographics

Supplemental material

A single PDF file includes all supplemental material except videos and spreadsheets. See

“Methods” above for large data sets

Before submission, carefully review all supplemental files; they will not be checked by a copy editor. The Journal is not responsible for any errors contained in supplemental material.

Supplemental document 3 | CONSORT (*Consolidated Standards of Reporting Trials*) checklist

Section/Topic	Item No	Checklist item	Reported on page No.
Title and abstract			
	1a	Identification as a randomized trial in the title or abstract	1 (Title) 4 (abstract)
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	26-27, Figure 1
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	4, 7-9
	2b	Specific objectives or hypotheses	4, 26-27
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	26-27
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	none
Participants	4a	Eligibility criteria for participants	26, 32, Supp. Document 2
	4b	Settings and locations where the data were collected	32
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	26-27, Supp. Table 1
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	26-27
	6b	Any changes to trial outcomes after the trial commenced, with reasons	none
Sample size	7a	How sample size was determined	26
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomization:			
Sequence generation	8a	Method used to generate the random allocation sequence	26
	8b	Type of randomization; details of any restriction (such as blocking and block size)	26
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	N/A
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	26

Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	N/A
	11b	If relevant, description of the similarity of interventions	26
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	26, 31-32
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	26, 31-32
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analyzed for the primary outcome	Figure 1
	13b	For each group, losses and exclusions after randomization, together with reasons	Figure 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	26, 32
	14b	Why the trial ended or was stopped	N/A
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 1
Numbers analyzed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	26, Fig 1
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Figures 3, 4 Table 2
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	Table 2
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	26-27
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	13
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	23-24
Generalizability	21	Generalizability (external validity, applicability) of the trial findings	24-25
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	20-25
Other information			
Registration	23	Registration number and name of trial registry	4, 32
Protocol	24	Where the full trial protocol can be accessed, if available	32
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	5, 34