ICMJE DISCLOSURE FORM

Date: 1/3/2023

Your Name: Diana C. Gomez Manjarrres

Manuscript Title: Sirolimus suppresses fibrocytes in idiopathic pulmonary fibrosis: A short term randomized controlled crossover trial

Manuscript Number (if known): 166901-INS-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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3	Royalties or licenses	☒ **None**	

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7	Support for attending meetings and/or travel	☒ **None**	
8	Patents planned, issued or pending	☒ **None**	
9	Participation on a Data Safety Monitoring Board or Advisory Board	☒ **None**	
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11	Stock or stock options	☒ **None**	
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	☒ **None**	
13	Other financial or non-financial interests	☒ **None**	

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Date: 1/3/2023

Your Name: Dierdre B. Axell-House

Manuscript Title: Sirolimus suppresses fibrocytes in idiopathic pulmonary fibrosis: A short term randomized controlled crossover trial

Manuscript Number (if known): 166901-INS-CMED-1

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Date: 1/3/2023

Your Name: Divya Patel

Manuscript Title: Sirolimus suppresses fibrocytes in idiopathic pulmonary fibrosis: A short term randomized controlled crossover trial

Manuscript Number (if known): 166901-INS-CMED-1

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		Galecto	Clinical Trial Site PI
		Boehringer Ingelheim	Clinical Trial Site PI
		BMS	Clinical Trial Site SubI
		Fibrogen	Clinical Trial Site SubI
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Date: 1/3/2023

Your Name: John Odackal

Manuscript Title: Sirolimus suppresses fibrocytes in idiopathic pulmonary fibrosis: A short term randomized controlled crossover trial

Manuscript Number (if known): 166901-INS-CMED-1

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Date: 1/3/2023

Your Name: Victor Yu

Manuscript Title: Sirolimus suppresses fibrocytes in idiopathic pulmonary fibrosis: A short term randomized controlled crossover trial

Manuscript Number (if known): 166901-INS-CMED-1

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ICMJE DISCLOSURE FORM

Date: 1/3/2023

Your Name: Marie Burdick

Manuscript Title: Sirolimus suppresses fibrocytes in idiopathic pulmonary fibrosis: A short term randomized controlled crossover trial

Manuscript Number (if known): 166901-INS-CMED-1

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Your Name: Borna Mehrad

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		NIH R01HL098329	
		American Heart Association 18TPA34170486	
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CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	3
	2b	Specific objectives or hypotheses	4
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	11
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	N/a
Participants	4a	Eligibility criteria for participants	Supp 2
	4b	Settings and locations where the data were collected	13
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	11, supp 3
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	11
	6b	Any changes to trial outcomes after the trial commenced, with reasons	N/a
Sample size	7a	How sample size was determined	13
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/a
Randomisation:			
Sequence	8a	Method used to generate the random allocation sequence	Supp 3

generation	8b	Type of randomisation; details of any restriction (such as blocking and block size)	N/a
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	Supp 3
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	11
	11b	If relevant, description of the similarity of interventions	Supp 4
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	13
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	N/a
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 analysed for the primary outcome	Fig 2
	13b	For each group, losses and exclusions after randomisation, together with reasons	Fig 2
Recruitment	14a	Dates defining the periods of recruitment and follow-up	11
	14b	Why the trial ended or was stopped	13
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 1
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Fig 2
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)	Fig 3-4
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	N/a
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	N/a

Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	Fig 2, Table 2
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	9-10
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	9-10
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	10
Other information			
Registration	23	Registration number and name of trial registry	2
Protocol	24	Where the full trial protocol can be accessed, if available	Supplement
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	2

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.