

ICMJE DISCLOSURE FORM

Date: 6/28/2023

Your Name: Marina Vivarelli

Manuscript Title: AUTOLOGOUS MESENCHYMAL STROMAL CELLS FOR SEVERE STEROID-DEPENDENT NEPHROTIC SYNDROME: THE MESNEPH STUDY

Manuscript Number (if known): 169424-INS-CMED-TR-2

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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	Name all entities with whom you have this relationship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)						
Time frame: Since the initial planning of the work								
1	All support for the present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.) No time limit for this item.	<input type="checkbox"/> None <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 5px;"> <tr> <td style="width: 80%;">AIFA Ricerca Indipendente 2016-02364623</td> <td style="width: 20%;"></td> </tr> <tr> <td> </td> <td> </td> </tr> <tr> <td colspan="2" style="text-align: right; font-size: small;">Click the tab key to add additional rows.</td> </tr> </table>	AIFA Ricerca Indipendente 2016-02364623				Click the tab key to add additional rows.	
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Time frame: past 36 months								
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3	Royalties or licenses	<input checked="" type="checkbox"/> None <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 5px;"> <tr> <td style="width: 80%;"> </td> <td style="width: 20%;"> </td> </tr> <tr> <td> </td> <td> </td> </tr> <tr> <td> </td> <td> </td> </tr> </table>						

		Name all entities with whom you have this relationship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
4	Consulting fees	<input type="checkbox"/> None	
		consulting/advisory board fees from Apellis, Chemocentrix, Biocryst, Novartis, Roche, Chinook, Bayer, PureSpring, Travers pharmaceuticals	
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	<input type="checkbox"/> None	
		lectures sponsored by Glaxo, Roche, Alexion, WebMD and participates in clinical trials sponsored by Alexion, Novartis, Bayer, Roche, Chinook, Apellis, Travers	
6	Payment for expert testimony	<input checked="" type="checkbox"/> None	
7	Support for attending meetings and/or travel	<input checked="" type="checkbox"/> None	
8	Patents planned, issued or pending	<input checked="" type="checkbox"/> None	
9	Participation on a Data Safety Monitoring Board or Advisory Board	<input checked="" type="checkbox"/> None	
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	<input checked="" type="checkbox"/> None	

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11	Stock or stock options	<input checked="" type="checkbox"/> None <table border="1" style="width: 100%; border-collapse: collapse;"> <tr><td style="width: 50%; height: 15px;"></td><td style="width: 50%;"></td></tr> <tr><td style="height: 15px;"></td><td></td></tr> <tr><td style="height: 15px;"></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" style="width: 100%; border-collapse: collapse;"> <tr><td style="width: 50%; height: 15px;"></td><td style="width: 50%;"></td></tr> <tr><td style="height: 15px;"></td><td></td></tr> <tr><td style="height: 15px;"></td><td></td></tr> </table>							
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Date: 6/30/2023

Your Name: Manuela Colucci

Manuscript Title: AUTOLOGOUS MESENCHYMAL STROMAL CELLS FOR SEVERE STEROID-DEPENDENT NEPHROTIC SYNDROME: THE MESNEPH STUDY

Manuscript Number (if known): 169424-INS-CMED-TR-2

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Your Name: MATTIA ALGERI

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ICMJE DISCLOSURE FORM

Date: Click or tap to enter a date. 23-06-2023
Your Name: Click or tap here to enter text. FEDERICA FORTA
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Click the tab key to add additional rows.
No time limit for this item.

Time frame: past 36 months

2 Grants or contracts from any entity (if not indicated in item #1 above). **None**

3 Royalties or licenses **None**

4 Consulting fees **None**

5 Payment or honoraria for lectures, presentations, **None**

speakers bureaus, manuscript writing or educational events	
6 Payment for expert testimony	<input checked="" type="checkbox"/> None
7 Support for attending meetings and/or travel	<input checked="" type="checkbox"/> None
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10 Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	<input checked="" type="checkbox"/> None
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Teoh Siew

ICMJE DISCLOSURE FORM

Date: 6/28/2023

Your Name: Francesco Emma

Manuscript Title: AUTOLOGOUS MESENCHYMAL STROMAL CELLS FOR SEVERE STEROID-DEPENDENT NEPHROTIC SYNDROME: THE MESNEPH STUDY

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Manuscript Number (if known): 169424-INS-CMED-TR-2

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: 6/30/2023

Your Name: Marco Busutti

Manuscript Title: AUTOLOGOUS MESENCHYMAL STROMAL CELLS FOR SEVERE STEROID-DEPENDENT NEPHROTIC SYNDROME: THE MESNEPH STUDY

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Date: 6/29/2023

Your Name: Stefano Rota

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Your Name: CHIARA CAPELLI

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ICMJE DISCLOSURE FORM

Date: 6/29/2023

Your Name: Martino Introna

Manuscript Title: AUTOLOGOUS MESENCHYMAL STROMAL CELLS FOR SEVERE STEROID-DEPENDENT NEPHROTIC SYNDROME: THE MESNEPH STUDY

Manuscript Number (if known): 169424-INS-CMED-TR-2

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ICMJE DISCLOSURE FORM

Date: 6/26/2023

Your Name: Marta Todeschini

Manuscript Title: AUTOLOGOUS MESENCHYMAL STROMAL CELLS FOR SEVERE STEROID-DEPENDENT NEPHROTIC SYNDROME: THE MESNEPH STUDY

Manuscript Number (if known): 169424-INS-CMED-TR-2

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ICMJE DISCLOSURE FORM

Date: 6/26/2023

Your Name: Federica Casiraghi

Manuscript Title: AUTOLOGOUS MESENCHYMAL STROMAL CELLS FOR SEVERE STEROID-DEPENDENT NEPHROTIC SYNDROME: THE MESNEPH STUDY

Manuscript Number (if known): 169424-INS-CMED-TR-2

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ICMJE DISCLOSURE FORM

Date: 6/7/2023

Your Name: ANNALISA PERNA

Manuscript Title: AUTOLOGOUS MESENCHYMAL STROMAL CELLS FOR SEVERE STEROID-DEPENDENT NEPHROTIC SYNDROME: THE MESNEPH STUDY

Manuscript Number (if known): 169424-INS-CMED-TR-2

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I certify that I have answered every question and have not altered the wording of any of the questions on this form.

ICMJE DISCLOSURE FORM

Date: 6/29/2023

Your Name: Tobia Peracchi

Manuscript Title: AUTOLOGOUS MESENCHYMAL STROMAL CELLS FOR SEVERE STEROID-DEPENDENT NEPHROTIC SYNDROME: THE MESNEPH STUDY

Manuscript Number (if known): 169424-INS-CMED-TR-2

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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I certify that I have answered every question and have not altered the wording of any of the questions on this form.

ICMJE DISCLOSURE FORM

Date: 6/30/2023

Your Name: Andrea De Salvo

Manuscript Title: AUTOLOGOUS MESENCHYMAL STROMAL CELLS FOR SEVERE STEROID-DEPENDENT NEPHROTIC SYNDROME: THE MESNEPH STUDY

Manuscript Number (if known): 169424-INS-CMED-TR-2

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: 6/29/2023

Your Name: Nadia Rubis

Manuscript Title: AUTOLOGOUS MESENCHYMAL STROMAL CELLS FOR SEVERE STEROID-DEPENDENT NEPHROTIC SYNDROME: THE MESNEPH STUDY

Manuscript Number (if known): 169424-INS-CMED-TR-2

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ICMJE DISCLOSURE FORM

Date: July 10, 2023

Your Name: Franco Locatelli

Manuscript Title: AUTOLOGOUS MESENCHYMAL STROMAL CELLS FOR SEVERE STEROID-DEPENDENT NEPHROTIC SYNDROME: THE MESNEPH STUDY

Manuscript Number (if known): 169424-INS-CMED-TR-2

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4	Consulting fees	<input checked="" type="checkbox"/> None	
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	<input checked="" type="checkbox"/> None	
6	Payment for expert testimony	<input checked="" type="checkbox"/> None	
7	Support for attending meetings and/or travel	<input checked="" type="checkbox"/> None	
8	Patents planned, issued or pending	<input checked="" type="checkbox"/> None	
9	Participation on a Data Safety Monitoring Board or Advisory Board	<input checked="" type="checkbox"/> None	
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	<input type="checkbox"/> None	
		<ul style="list-style-type: none"> • President of the Italian Higher Council of Health, the technical scientific advisory body to the Ministry of Health. 	Since 2019
		<ul style="list-style-type: none"> • Coordinator of the Technical-Scientific Committee for the COVID-19 pandemic 	From March 2021 till March 2022

		Name all entities with whom you have this relationship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
11	Stock or stock options	<input checked="" type="checkbox"/> None	
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	<input checked="" type="checkbox"/> None	
13	Other financial or non-financial interests	<input checked="" type="checkbox"/> None	

Please place an "X" next to the following statement to indicate your agreement:

I certify that I have answered every question and have not altered the wording of any of the questions on this form.



ICMJE DISCLOSURE FORM

Date: 6/30/2023

Your Name: GIUSEPPE REMUZZI

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Date: 6/30/2023

Your Name: Piero Ruggenti

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


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TREND Statement Checklist

Paper Section/ Topic	Item No	Descriptor	Reported?	
				Pg #
Title and Abstract				
Title and Abstract	1	• Information on how unit were allocated to interventions		2
		• Structured abstract recommended		2
		• Information on target population or study sample		2
Introduction				
Background	2	• Scientific background and explanation of rationale		3-5
		• Theories used in designing behavioral interventions		3-5
Methods				
Participants	3	• Eligibility criteria for participants, including criteria at different levels in recruitment/sampling plan (e.g., cities, clinics, subjects)		14-15
		Method of recruitment (e.g., referral, self-selection), including the sampling method if a systematic sampling plan was implemented		14-15
		• Recruitment setting		14-15
		• Settings and locations where the data were collected		14-15
Interventions	4	• Details of the interventions intended for each study condition and how and when they were actually administered, specifically including:		15-16
		○ Content: what was given?		15-16
		○ Delivery method: how was the content given?		15-16
		○ Unit of delivery: how were the subjects grouped during delivery?		15-16
		○ Deliverer: who delivered the intervention?		15-16
		○ Setting: where was the intervention delivered?		15-16
		○ Exposure quantity and duration: how many sessions or episodes or events were intended to be delivered? How long were they intended to last?		15-16
		○ Time span: how long was it intended to take to deliver the intervention to each unit?		15-16
		○ Activities to increase compliance or adherence (e.g., incentives)		17
Objectives	5	• Specific objectives and hypotheses		17-18
Outcomes	6	• Clearly defined primary and secondary outcome measures		17-18
		• Methods used to collect data and any methods used to enhance the quality of measurements		16-17 20-22
		• Information on validated instruments such as psychometric and biometric properties		16-19
Sample Size	7	How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules		17 20-21
Assignment Method	8	Unit of assignment (the unit being assigned to study condition, e.g., individual, group, community)		14
		Method used to assign units to study conditions, including details of any restriction (e.g., blocking, stratification, minimization)		14
		Inclusion of aspects employed to help minimize potential bias induced due to non-randomization (e.g., matching)		14 20-22

TREND Statement Checklist

Blinding (masking)	9	<ul style="list-style-type: none"> Whether or not participants, those administering the interventions, and those assessing the outcomes were blinded to study condition assignment; if so, statement regarding how the blinding was accomplished and how it was assessed. 		14
Unit of Analysis	10	<ul style="list-style-type: none"> Description of the smallest unit that is being analyzed to assess intervention effects (e.g., individual, group, or community) 		20-22
		<ul style="list-style-type: none"> If the unit of analysis differs from the unit of assignment, the analytical method used to account for this (e.g., adjusting the standard error estimates by the design effect or using multilevel analysis) 		20-22
Statistical Methods	11	<ul style="list-style-type: none"> Statistical methods used to compare study groups for primary methods outcome(s), including complex methods of correlated data 		20-22
		<ul style="list-style-type: none"> Statistical methods used for additional analyses, such as a subgroup analyses and adjusted analysis 		20-22
		Methods for imputing missing data, if used		20-22
		Statistical software or programs used		22
Results				
Participant flow	12	Flow of participants through each stage of the study: enrollment, assignment, allocation, and intervention exposure, follow-up, analysis (a diagram is strongly recommended)		6
		<ul style="list-style-type: none"> Enrollment: the numbers of participants screened for eligibility, found to be eligible or not eligible, declined to be enrolled, and enrolled in the study 		6
		<ul style="list-style-type: none"> Assignment: the numbers of participants assigned to a study condition 		6
		<ul style="list-style-type: none"> Allocation and intervention exposure: the number of participants assigned to each study condition and the number of participants who received each intervention 		6
		<ul style="list-style-type: none"> Follow-up: the number of participants who completed the follow-up or did not complete the follow-up (i.e., lost to follow-up), by study condition 		6- Fig1
		<ul style="list-style-type: none"> Analysis: the number of participants included in or excluded from the main analysis, by study condition 		6- Fig1
		<ul style="list-style-type: none"> Description of protocol deviations from study as planned, along with reasons 		6
Recruitment	13	Dates defining the periods of recruitment and follow-up		6- Table S2
Baseline Data	14	Baseline demographic and clinical characteristics of participants in each study condition		6- Table 1-4
		Baseline characteristics for each study condition relevant to specific disease prevention research		6- Table 1-4
		Baseline comparisons of those lost to follow-up and those retained, overall and by study condition		6
		Comparison between study population at baseline and target population of interest		6- Table 1-4

TREND Statement Checklist

Baseline equivalence	15	<ul style="list-style-type: none"> Data on study group equivalence at baseline and statistical methods used to control for baseline differences 		6-Table 1-4
Numbers analyzed	16	<ul style="list-style-type: none"> Number of participants (denominator) included in each analysis for each study condition, particularly when the denominators change for different outcomes; statement of the results in absolute numbers when feasible 		6-10 Fig 2-4 Table 4
		<ul style="list-style-type: none"> Indication of whether the analysis strategy was “intention to treat” or, if not, description of how non-compliers were treated in the analyses 		6-9
Outcomes and estimation	17	<ul style="list-style-type: none"> For each primary and secondary outcome, a summary of results for each estimation study condition, and the estimated effect size and a confidence interval to indicate the precision 		7-10 Fig 2-3-4
		<ul style="list-style-type: none"> Inclusion of null and negative findings 		7-10
		<ul style="list-style-type: none"> Inclusion of results from testing pre-specified causal pathways through which the intervention was intended to operate, if any 		10
Ancillary analyses	18	<ul style="list-style-type: none"> Summary of other analyses performed, including subgroup or restricted analyses, indicating which are pre-specified or exploratory 		9
Adverse events	19	<ul style="list-style-type: none"> Summary of all important adverse events or unintended effects in each study condition (including summary measures, effect size estimates, and confidence intervals) 		6-7 Tab 2-3
DISCUSSION				
Interpretation	20	<ul style="list-style-type: none"> Interpretation of the results, taking into account study hypotheses, sources of potential bias, imprecision of measures, multiplicative analyses, and other limitations or weaknesses of the study 		10-14
		<ul style="list-style-type: none"> Discussion of results taking into account the mechanism by which the intervention was intended to work (causal pathways) or alternative mechanisms or explanations 		10-14
		<ul style="list-style-type: none"> Discussion of the success of and barriers to implementing the intervention, fidelity of implementation 		13-14
		<ul style="list-style-type: none"> Discussion of research, programmatic, or policy implications 		13-14
Generalizability	21	<ul style="list-style-type: none"> Generalizability (external validity) of the trial findings, taking into account the study population, the characteristics of the intervention, length of follow-up, incentives, compliance rates, specific sites/settings involved in the study, and other contextual issues 		14
Overall Evidence	22	<ul style="list-style-type: none"> General interpretation of the results in the context of current evidence and current theory 		14

TREND Statement Checklist

*From: Des Jarlais, D. C., Lyles, C., Crepaz, N., & the Trend Group (2004). Improving the reporting quality of nonrandomized evaluations of behavioral and public health interventions: The TREND statement. *American Journal of Public Health*, 94, 361-366. For more information, visit: <http://www.cdc.gov/trendstatement/>*