

**Invitation for Expression of Interest for providing intravenous Doxycycline, intravenous Azithromycin, Matching Placebo and Blinded Drug Packets for a Randomized Controlled Trial**

Government Medical College and Hospital, Chandigarh is conducting a trial; titled “Efficacy in Scrub typhus of Combination therapy in Children versus Azithromycin or Doxycycline monotherapy: a double-blind Randomized control trial (ESCHAR Trial)”.

The PI is Dr Vidushi Mahajan, Department of Pediatrics, GMCH 32, Chandigarh.

This is a phase III, multi-centre, investigator-initiated, three-arm, parallel-group, stratified and block-randomized controlled trial. The primary objective is to compare doxycycline (DX) and azithromycin (AZ) monotherapy with combination (DX+AZ) therapy for a composite outcome consisting mortality within 14 days, persistent complications on day 7, and persistent fever ( $\geq 37.5^{\circ}\text{C}$ ) on day 5.

This study plans to recruit 700 children of 2 months to 18 years of age who develop severe scrub typhus at five study sites including GMCH, Chandigarh over 3 years (140 patients at each site participating site) and the duration of the trial is 3 years.

Request for proposals are invited from eligible pharmaceutical manufacturers who have experience in supplying injectable antibiotics under WHO-GMP compliant facilities as per ICMR ethical guidelines, for the aforementioned study.

The regulatory and quality requirements are:

1. Cold-chain maintenance and validated transport where applicable
  2. Complete documentation for batch release, quality assurance, and accountability
- Note-** Please download the ‘technical specifications’ for the details of the blinded drugs procurement (Doxycycline, Azithromycin and Matching Placebo) from the GMCH-32 website along with EOI.
3. You also need to sign the CONFIDENTIALITY AND NON-DISCLOSURE AGREEMENT for this trial. Please download the document attached to this EOI.

**SCHEDULE OF EOI PROCESS**

The Schedule of activities during the EOI Process shall be as follows-

Sl. No.	Description	Date
1.	Issue of EOI document	<b>05.02.2026</b>
2.	Last date of submission of EOI response	<b>Date extended to: 14.03.2026 5:00 p.m.</b>

Please submit your expression of interest to Email: [drvidushiicmr@gmail.com](mailto:drvidushiicmr@gmail.com) with complete documentation. Please email on the above-mentioned email address if you need any further clarification. Please submit the hard copy to the following address:

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Dr Vidushi Mahajan  
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GMCH, Sector 32  
Chandigarh 160030  
Tel +91-172- 2665252-60 Extn. 2503 (Office)

*27/2/26*

**Technical Specifications: Procurement of Blinded Drugs (Intravenous Doxycycline, Intravenous Azithromycin and Matching Placebo)**

**Project: "IIRPIG-2025-01-00586 Efficacy in Scrub typhus of Combination therapy in Children versus Azithromycin or Doxycycline monotherapy: a double-blind Randomized control trial (ESCHAR TRIAL)."**

S.No.	Item	Specification																																			
1.	Phase of trial and sponsor	Clinical trial (Phase III) sponsored by Indian Council of Medical Research (ICMR), New Delhi																																			
2.	Sites of the trial	Clinical trial will be conducted at Government Medical College & Hospital (GMCH 32), Chandigarh, IGMC Shimla, RPGMC Tanda, AIIMS Rishikesh, AIIMS Bhubaneswar																																			
3.	Sample size	Total sample size: 700																																			
4.	Trial design	Three arm double blind randomized control trial.																																			
5.	Treatment Arms	Three parallel arms: Arm 1: Intravenous Doxycycline + Placebo Arm 2: Intravenous Azithromycin + Placebo Arm 3: Intravenous Doxycycline + Intravenous Azithromycin.																																			
6.	Weight-Based Stratification	<table border="1"> <thead> <tr> <th>Weight band (Kg)</th> <th>No. of patients</th> <th>Total</th> </tr> </thead> <tbody> <tr> <td>&lt;=10 kg</td> <td>70</td> <td rowspan="5">700</td> </tr> <tr> <td>11-20</td> <td>140</td> </tr> <tr> <td>21-30</td> <td>210</td> </tr> <tr> <td>31-40</td> <td>210</td> </tr> <tr> <td>&gt;40</td> <td>70</td> </tr> </tbody> </table>	Weight band (Kg)	No. of patients	Total	<=10 kg	70	700	11-20	140	21-30	210	31-40	210	>40	70																					
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7.	Drug requirements	Intravenous doxycycline, intravenous azithromycin, matched intravenous placebo and blinded drug packets																																			
8.	Packaging Requirements	<p>This is a 3-parallel arm trial. As doxycycline is prescribed as a BD dosage, we will give azithromycin in BD dosage to preserve blinding. So, each child will be randomly assigned to either:</p> <ul style="list-style-type: none"> <li>• Arm 1: DX+ placebo</li> <li>• Arm 2: AZ+ placebo</li> <li>• Arm 3: DX+AZ</li> </ul> <table border="1"> <thead> <tr> <th>Weight band (Kg)</th> <th>No. of patients</th> <th colspan="3">Expected number of Patients in 3 treatment arms</th> </tr> <tr> <td></td> <td></td> <th>Arm 1:</th> <th>Arm 2:</th> <th>Arm 3:</th> </tr> </thead> <tbody> <tr> <td>&lt;=10 kg</td> <td>70</td> <td>23</td> <td>23</td> <td>23</td> </tr> <tr> <td>11-20</td> <td>140</td> <td>47</td> <td>47</td> <td>47</td> </tr> <tr> <td>21-30</td> <td>210</td> <td>70</td> <td>70</td> <td>70</td> </tr> <tr> <td>31-40</td> <td>210</td> <td>70</td> <td>70</td> <td>70</td> </tr> <tr> <td>&gt;40</td> <td>70</td> <td>23</td> <td>23</td> <td>23</td> </tr> </tbody> </table>	Weight band (Kg)	No. of patients	Expected number of Patients in 3 treatment arms					Arm 1:	Arm 2:	Arm 3:	<=10 kg	70	23	23	23	11-20	140	47	47	47	21-30	210	70	70	70	31-40	210	70	70	70	>40	70	23	23	23
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		<p>Number of injections per package per patient (weight band based) over 3 years:</p> <table border="0" style="width: 100%; text-align: center;"> <tr> <td style="width: 33%; vertical-align: top;"> <p>Arm 1/Package 1</p> <p>↓</p> <p>28 Injections: 14 IV DX+14 IV Placebo</p> <p>↓</p> <p>≤10 kg: 23 packages  11-20 kg: 47 packages  21-30 kg: 70 packages  31-40 kg: 70 packages  &gt;40 kg: 23 packages  Total no. of packages: 233(3 years)  Total injections in arm 1 over 3 years: 233 X 28 injections per patient = 6524 injections</p> </td> <td style="width: 33%; vertical-align: top;"> <p>Arm 2/Package 2</p> <p>↓</p> <p>28 Injections: 14 IV AZ+14 IV Placebo</p> <p>↓</p> <p>≤10 kg: 23 packages  11-20 kg: 47 packages  21-30 kg: 70 packages  31-40 kg: 70 packages  &gt;40 kg: 232 packages  Total no. of packages: 233 (3 years)  Total injections in arm 2 over 3 years: 233 X 28 injections per patient = 6524 injections</p> </td> <td style="width: 33%; vertical-align: top;"> <p>Arm 3/Package 3</p> <p>↓</p> <p>28 Injections: 14 IV DX+14 IV AZ</p> <p>↓</p> <p>≤10 kg: 23 packages  11-20 kg: 47 packages  21-30 kg: 70 packages  31-40 kg: 70 packages  &gt;40 kg: 23 packages  Total no. of packages: 233 (3 years)  Total injections in arm 3 over 3 years: 233 X 28 injections per patient =6524 injections</p> </td> </tr> </table>	<p>Arm 1/Package 1</p> <p>↓</p> <p>28 Injections: 14 IV DX+14 IV Placebo</p> <p>↓</p> <p>≤10 kg: 23 packages  11-20 kg: 47 packages  21-30 kg: 70 packages  31-40 kg: 70 packages  &gt;40 kg: 23 packages  Total no. of packages: 233(3 years)  Total injections in arm 1 over 3 years: 233 X 28 injections per patient = 6524 injections</p>	<p>Arm 2/Package 2</p> <p>↓</p> <p>28 Injections: 14 IV AZ+14 IV Placebo</p> <p>↓</p> <p>≤10 kg: 23 packages  11-20 kg: 47 packages  21-30 kg: 70 packages  31-40 kg: 70 packages  &gt;40 kg: 232 packages  Total no. of packages: 233 (3 years)  Total injections in arm 2 over 3 years: 233 X 28 injections per patient = 6524 injections</p>	<p>Arm 3/Package 3</p> <p>↓</p> <p>28 Injections: 14 IV DX+14 IV AZ</p> <p>↓</p> <p>≤10 kg: 23 packages  11-20 kg: 47 packages  21-30 kg: 70 packages  31-40 kg: 70 packages  &gt;40 kg: 23 packages  Total no. of packages: 233 (3 years)  Total injections in arm 3 over 3 years: 233 X 28 injections per patient =6524 injections</p>
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9.	Quantity Estimation	<p>Arm 1: Total 6524 injections of blinded IV Doxycycline and blinded matching IV placebo</p> <p>Arm 2: Total 6524 injections of blinded IV Azithromycin and blinded matching IV placebo</p> <p>Arm 3: Total 6524 injections of blinded IV Doxycycline + blinded IV Azithromycin</p>			
10.	Distribution Plan	Centralized preparation and distribution of blinded kits to nodal trial site (GMCH 32 Chandigarh). Buffer stock to be maintained.			
11.	Labeling	Blinded labels without drug identity; include protocol number, randomization code, weight band, dosing schedule, storage conditions			
12.	Storage & Transport	Cold chain maintained as per manufacturer specifications. Temperature monitoring required during transport and storage.			

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13.	Regulatory Compliance	Manufacturing under WHO-GMP conditions. Compliance with ICMR ethical guidelines.
14.	Accountability & Returns	Complete drug accountability logs to be maintained. Unused/expired kits returned or destroyed as per ICMR instructions.

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