A human controlled infection study to assess colonisation and immunogenicity following nasal inoculation with *Neisseria lactamica* with eradication on Day 4 or 14

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**Introduction**

*Neisseria lactamica* is a non-virulent nasopharyngeal commensal, particularly found in young children. It is closely related to *Neisseria meningitidis*, which is often carried asymptomatically but in a minority of individuals causes invasive disease.

Previous studies have shown an inverse relationship between colonisation with *N. lactamica* and *N. meningitidis*. Longstanding colonisation with *N. lactamica* can be induced by nasal inoculation in healthy volunteers and prevents or displaces colonisation with *N. meningitidis*. It also results in the production of some cross-reactive antibodies against *N. meningitidis* although not those which are protective against invasive meningococcal disease.

Future research studies will aim to improve the rate and duration of colonisation following challenge with *N. lactamica*, and the induction of *N. meningitidis* specific serum bactericidal activity. This pilot study will yield information necessary for the optimal design of future studies.

**Aims**

Comparison of 4 day (Group 1) versus 14 day (Group 2) *N. lactamica* colonisation on systemic and mucosal immunogenicity.

Assessment of efficacy of oral Ciprofloxacin in eradicating nasal *Neisseria lactamica* colonisation by 24 hours after treatment.

**Methods**

Healthy adult volunteers will be screened to exclude smoking and nasal carriage of *N. meningitidis* or *N. lactamica*. Enrolled volunteers will be nasally inoculated with a total of 10^5 cfu in 1 ml wild type *N. lactamica*.

Ciprofloxacin eradication therapy will be given at Day 4 (Group 1) or Day 14 (Group 2). Colonisation, efficacy of eradication and immunogenicity will be assessed up to 28 days post eradication.

**Group 1**

<table>
<thead>
<tr>
<th>Day</th>
<th>Screening</th>
<th>Baseline immunology</th>
<th>Inoculation</th>
<th>Assess colonisation</th>
<th>Eradication</th>
<th>Assess eradication</th>
<th>Immunology</th>
<th>Re-assess eradication</th>
<th>Immunology</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤90</td>
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<td>4</td>
<td>5</td>
<td>14</td>
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**Group 2**

<table>
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<th>Day</th>
<th>Screening</th>
<th>Baseline immunology</th>
<th>Inoculation</th>
<th>Assess colonisation</th>
<th>Eradication</th>
<th>Assess eradication</th>
<th>Immunology</th>
</tr>
</thead>
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</tr>
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</table>

**Study progress:**

8 people have been inoculated so far. Group 1 has shown a colonisation rate of 20% by Day 4. Group 2 has shown a colonisation rate of 33% by Day 4 and 100% by Day 7. Eradication therapy has cleared colonisation in all of those colonised and no participants have become colonised following eradication. There have been no safety concerns.