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

Diane Gbesemete[1,3], **Hans de Graaf**[1,3], **Jay Laver**[3], **Muktar Ibrahim**[3], **Andrew Gorringe**[4], **Saul Faust**[1,3], **Robert Read**[2,3]

1 NIHR Clinical Research Facility, University Hospital Southampton, 2 NIHR Southampton Biomedical Research Centre, University Hospital Southampton, 3 Clinical & Experimental Sciences, Faculty of Medicine, University of Southampton, 4 Public Health England, Porton Down, Salisbury

Introduction

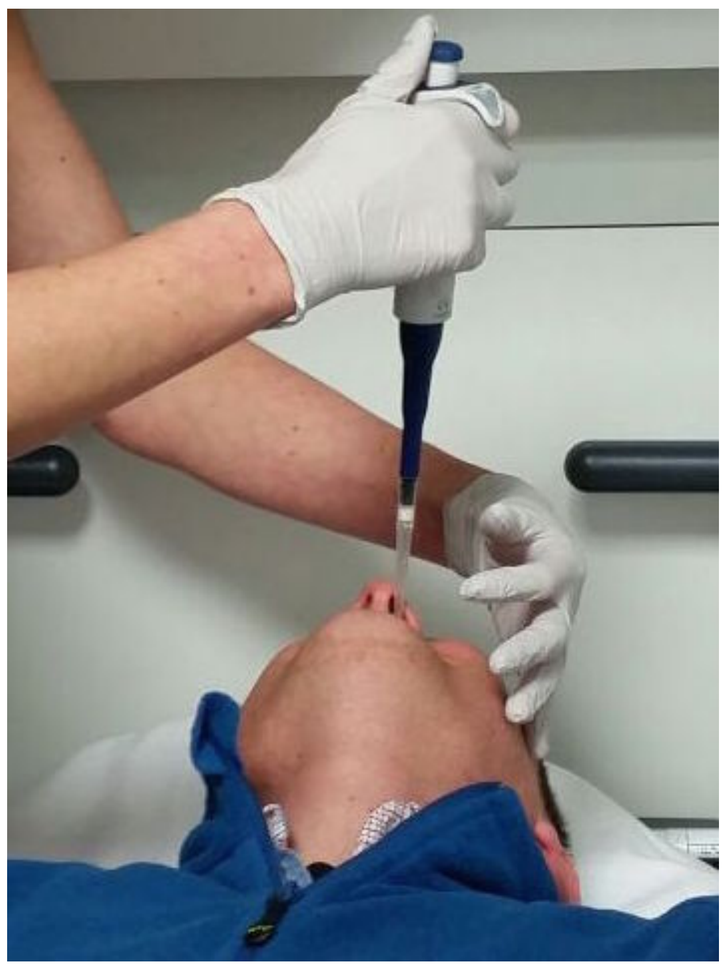
Neisseria lactamica is a non-virulent nasopharyngeal commensal, particularly found in young children. It is closely related to *Neisseria meningitidis,* which is often carried asymptomatically but in a minority of individuals causes invasive disease.

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

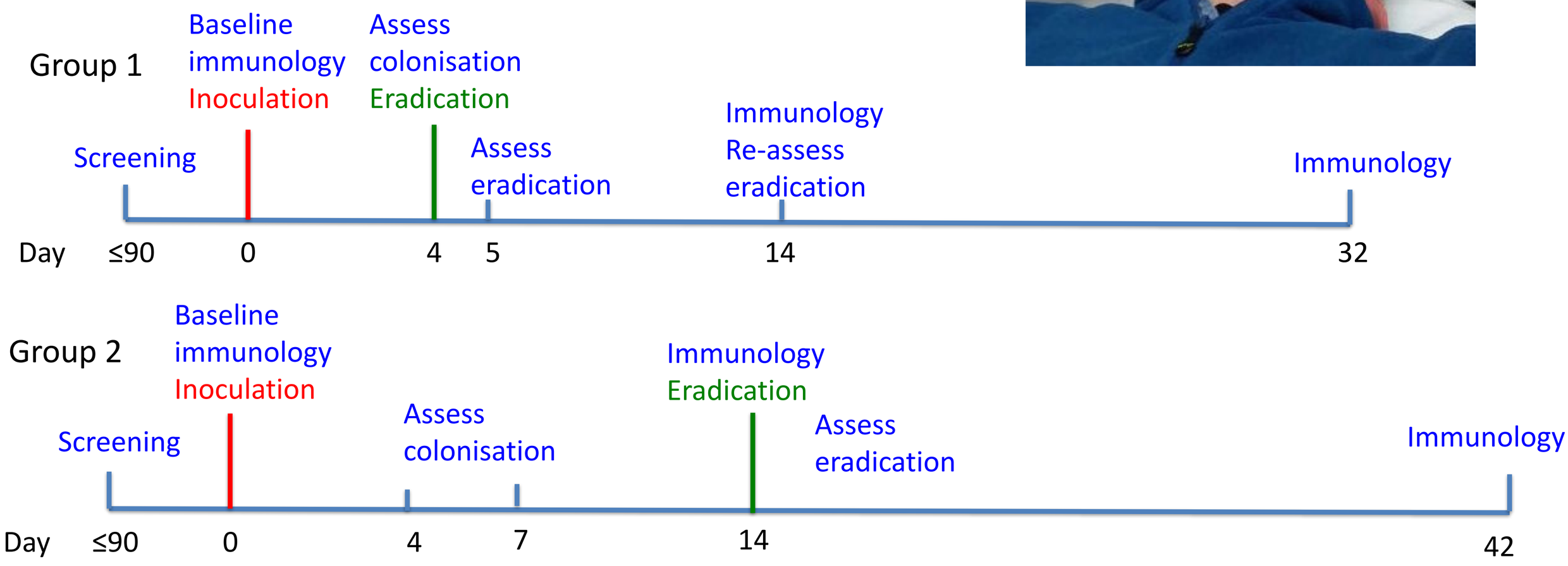
Comparison of 4 day (Group 1) versus 14 day (Group 2) *N. lactamica* colonisation on systemic and mucosal immunogenicity.
Assessment of efficacy of oral Ciprofloxacin in eradicating nasal *Neisseria lactamica* colonisation by 24 hours after treatment.



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.



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.

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