



Evaluating a new vaccine for the prevention of whooping cough

Dear Parent/legal guardian,

We are writing to inform you about an important research study taking place at our site, that is looking at a new vaccine against pertussis (whooping cough). As part of this study, we would be inviting your child/teenager to receive either the new vaccine we are studying, or an existing approved vaccine against pertussis.

This is an international study enrolling 600 children/teenagers aged 6 to 16 years old and is being funded by a company called ILiAD Biotechnologies.

Pertussis is a highly contagious disease which is transmitted via one's airways by a bacteria called *Bordetella pertussis*. There are epidemics of pertussis every 3-5 years. If left untreated, the bacteria can cause extreme repeated coughing spells that can last for months. In some instances, when this bacteria is spread to small infants it can be potentially life-threatening. It is worse in those very young, or those who have not received a vaccination against pertussis, however the outbreaks of pertussis in school age children (ages 6-16) have significantly increased in the United Kingdom. These outbreaks are occurring even though students have received current pertussis vaccines during early childhood.

What is the SUPER study?

- This study will measure the effects of a new vaccine and compare them to those of an already approved vaccine against pertussis
- Children/teenagers who take part will receive a dose of the study vaccine (a spray up the nose) and/or a dose of an approved vaccine against pertussis (an injection in the arm)
- Prior to receiving the vaccination the COVID-19 test must be negative
- A few study participants, if willing, will also receive another dose of the study vaccine (a spray in the nose) after about 3 months and this will require some extra visits. This is an optional part of the study to be in.
- The study vaccine is not approved, so we do not know if it is effective in the prevention of pertussis. The approved vaccine has been proven to reduce the risk of pertussis. All study participants will be offered the approved vaccine after the study has completed, if approved by the treating physician.
- The main study will have about 4 site visits unless you decide to be in an optional part of the study and then a few more visit will be required. The study team will be collecting blood and nasal secretion samples at 4 of the main study visits. Additional samples will be collected if you are in the optional part of the study.

- As with many vaccines, immunisation with either the study or the approved vaccines can cause some discomfort at the injection site (nose or arm), and can be associated with short lived headaches, generalised aches and pains, or gastrointestinal upset.
- Visits will be held at our site Leicester Royal Infirmary.

Who decides if my child/teenager takes part?

Regardless of the age of your child, they will be informed about the study to the best of their understanding, and we will be seeking their agreement to participate. Older children, if able to, will be able to decide if they want to take part (consent) themselves, and will be provided with the full information describing the study in more detail.

If you would like any further information regarding the study, please contact the study team on:

Email: SUPERtrial@uhl-tr.nhs.uk

Tel: 07950851123

Many thanks,
Leicester Royal
Infirmary
The SUPER team