COVID-19

Oxford Vaccine Trial

Oxford COVID-19 vaccine study in children - FAQs

Building on previous trials of the ChAdOx1 nCoV-19 vaccine, which have shown that it is safe, produces strong immune system responses and has high efficacy in all adults, this trial will assess if children and young adults aged 6-17 years make a good immune response with the vaccine. Here are some FAQs the team has put together.

What is the study?

The COV006 study is a UK phase II study to assess the safety and immune response of the COVID-19 vaccine, ChAdOx1 nCoV-19, in healthy children aged 6-17 years old.

How many children will be taking part?

We expect to enrol up to 300 children at study sites in Oxford, Southampton, London and Bristol. Up to 150 participants aged 6-11 years and up to 150 participants aged 12-17 years will take part in the study.

How will the study work?

Participants will either receive the ChAdOx1 nCoV-19 vaccine or a control vaccine for meningitis, called MenB. All participants will receive two doses of the vaccine, half receiving the second dose after 4 weeks and half receiving the second dose after 12 weeks.

Participants and their parents will be asked to complete an e-diary for 28 days after receiving each dose of the vaccine to record any symptoms following vaccination. They will also have five blood tests throughout the study to assess the immune response to the vaccine.

How do children consent to take part in vaccine studies?

For children under the age of 16, their parents must give full informed consent and the child or young person must assent to taking part. Written assent is taken from children aged 11 – 16 and verbal assent is taken for those under the age of 11.

Young people aged 16-17 are able to self-consent as per the National Institute for Health Research guidelines, but they must be accompanied by a parent or guardian on their first visit and the parent/guardian will also receive information about the study.

I thought children didn't get COVID-19?

It's true that the majority of hospital admissions during the pandemic have been of older adults. However, there were a small number of children who did develop serious symptoms when they caught COVID-19 and required hospital admission (over 700 in the UK's first wave). Many of these children had pre-existing medical conditions which made them more susceptible to the effects of a virus which affects the lungs.

Paediatric doctors have also seen a new condition emerge, called PIMS-TS. It's an inflammatory syndrome which seems to be associated with COVID-19 disease (often occurring a few weeks after COVID-19 infection) but can make children very unwell, and some have required admission with multi-organ failure and admission to ITU. The number of children affected by this syndrome in the first wave was less than 100.

Why are you doing a trial now?

We are doing a trial now because we have a lot of data about the Oxford vaccine being safe in adults (it has been given to over 20,000 adults). It has been shown to be safe and effective.

We are not sure about the role that children play in transmitting the disease and this is something that we will find out more about as the pandemic progresses. But it is likely that vaccination will help in slowing the spread of the disease and it may be possible that vaccinating children will help with this too.

Is the vaccine likely to be effective in children?

In many respects, there are very few differences between older teenagers and young adults. We therefore expect the vaccine to be effective in these age groups.

What dose are you giving to children?

We are giving the same dose as we gave in the adult study. Many vaccines are given at the same dose in adults as in children.

The Oxford vaccine is based on a weakened virus which produces some of the proteins of the SARS-CoV-2 virus. This weakened virus has been given to teenagers in other trials at the same dose as is currently being used for adult administration of the Oxford vaccine and there were no serious side effects in those studies.

We will review our data at regular intervals during this trial and see if there is any evidence that a lower dose might be better for children.

Recruitment into the study will happen in stages. We will first give the vaccine to older teenagers (12-17 years) and therefore have the opportunity to review our data before we give it to younger children.

Will other manufacturers be doing paediatric studies too?

This is the first trial of a COVID-19 vaccine in this age group (6-17 years). Some trials have begun in teenagers (16/17 years). None of them are yet licensed for younger children.

If a child has been given the COVID-19 vaccine, does this mean they can visit their grandparents?

Even if your child has been given a COVID-19 vaccine, we don't know to what extent this reduces their risk of spreading the virus and how safe it is for grandparents, even if they have been vaccinating. We advise adhering to government regulations on social distancing.

Why aren't you enrolling children with medical conditions into this trial? Is it because the vaccine isn't safe?

This is a relatively small study (of 300 children) to look at the safety and effectiveness of the vaccine in younger children and teenagers. Because it is the first time it has been trialled in children, only healthy children will be enrolled, as part of the usual approach to evaluating vaccines.

What is the group B meningococcal vaccine (MenB), what are its side effects, and why are we using it in this study?

The MenB vaccine is a licensed vaccine against group B meningococcus which has been given routinely to babies in the UK since 2015 and protects against one of the most common causes of meningitis and sepsis.

The MenB vaccine is being used as an 'active control' vaccine in this study, to help us understand participants' response to ChAdOx1 nCoV-19. The reason for using this vaccine, rather than a saline control, is because we expect to see some minor side effects from the ChAdOx1 nCOV-19 vaccine such as a sore arm, headache and fever. Saline does not cause any of these side effects. If participants were to receive only this vaccine or a saline control, and went on to develop side effects, they would be aware that they had received the new vaccine. It is critical for this study that participants remain blinded to whether or not they have received the vaccine, as, if they knew, this could affect their health behaviour in the community following vaccination, and may lead to a bias in the results of the study.

Who is funding the study?

The study is funded by the National Institute for Health Research, a government funded research agency, with additional support from AstraZeneca. The results of the study will be made available to AstraZeneca to ensure that further development of the vaccine can continue rapidly if the results of the study show that the vaccine works in children.

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