BCG Vaccine – Current use, safety & skin test

The BCG vaccine is the only TB vaccine currently available, although there are other TB vaccines under development. Although far from perfect, the BCG vaccine is a relatively inexpensive, safe, and readily available vaccine that is still the only vaccine available for the prevention of human forms of TB.

Who is given the BCG vaccine?



A child being given the BCG vaccine in their upper right arm © AMREF Demsissew Bizuwork

The BCG vaccine is normally given to children as it has been shown to provide very good protection against the disseminated forms of <u>TB in children</u>, including TB meningitis. However the protection provided against pulmonary TB in adults is very variable. So the BCG vaccine is not generally given to adults.¹

The BCG vaccine is one of the most widely used of all current vaccines, and overall it reaches more than 80% of all new born children and infants in countries where it is part of the national childhood immunization programme.² The World Health Organisation (WHO) monitors the estimated coverage of the BCG vaccine in every country.³

Not every country that could do so gives the vaccine to all children. Generally countries where there is a high level of TB use the BCG vaccine to vaccinate all children. Some countries with a low level of TB, such as the United States and England do not give all children the vaccine, but only those considered at particular risk. The United States has never vaccinated all children, but in the United Kingdom all children were given the vaccine until 2005.⁴

BCG vaccine for babies in the UK

In the UK the BCG vaccine is recommended for all babies up to one year old who:

- are born in areas where the rates of TB are high
- have one or more parents or grandparents who were born in countries with a high incidence of TB.⁵

Newborn babies can be given the vaccine soon after birth. Infants less than 6 months of age do not need to be tested with a tuberculin skin test (the Mantoux test) before the administration of BCG, but those over six months of age do.⁶

BCG vaccine for older children in the UK

The BCG vaccination is recommended for all older children and adults at risk of TB including:

- older children with an increased risk of TB who were not vaccinated against TB when they were babies
- anyone under 16 who has come from an area where TB is widespread
- anyone under 16 who has been in close contact with someone who has pulmonary TB (TB infection of the lung).

The BCG vaccine and the TB skin test



A bottle containing BCG vaccine

People who have had the BCG vaccine will often then have a positive result to a <u>TB skin test</u>. This makes it more difficult to establish whether someone has <u>latent TB</u>. This is one of the reasons that the vaccine is not used in some countries.⁷

The skin test will often be given before BCG vaccination. If there is a positive result to the skin test indicating that the person already has some immunity to TB, then the BCG vaccination will not be given. Giving the BCG vaccine to someone who already has some immunity, provides no benefit and could cause unpleasant side effects.⁸

Shortage of BCG vaccine

There has been a shortage of the BCG vaccine in the European Union since April of 2015. It is now not expected that supplies will return to normal until 2017.⁹ In England it is said that supplies of BCG ran out in the summer of 2016.

BCG vaccine safety issues

In the early years of the use of the BCG vaccine there were some concerns about safety, and there was the Lubeck disaster. Subsequently for many years there was little concern about safety. However it is now considered that the use of the BCG vaccine in children who are immune compromised, such as children with HIV, could result in them having an infection caused by the BCG vaccine itself. This is because the BCG vaccine contains a live but very weakened form of a bacteria called Mycobacterium bovis. This is not the same bacteria though as the bacteria that causes TB in humans, which is called Mycobacterium tuberculosis.10 11

Replacing the BCG vaccine

The organisation AERAS was set up in 2003 to develop new, safe, effective and affordable vaccines to replace the BCG vaccine. A new vaccine will need to protect against all strains of TB including the different types of drug resistant TB. The vaccine will also need to be suitable for use in preventing TB in children, adolescents and adults, as well being safe for use in people who are infected with both HIV and TB.¹²

AERAS is supporting the clinical testing of six possible new TB vaccines any one of which could be a suitable vaccine to replace BCG. In October 2012 it was announced that in connection with Glaxo, AERAS will in 2013 begin a phase IIB study in Kenya, India and South Africa. It is planned that this vaccine if successful would be used alongside the existing BCG vaccine.¹³

Another potential TB vaccine also designed to be used in conjunction with BCG is MVA85A. In February 2013 the results were announced of a phase 2B trial of MVA85A.¹⁴ This disappointingly showed that MVA85A did not provide any significant effectiveness against either tuberculosis or M. tuberculosis infection, although some people considered that:

"the findings ... are not a terminal prognosis for MVA85A, or for any of the other tuberculosis vaccines in development."¹⁵

Read more

You can read more about the History of the bcg vaccine

or about <u>TB treatment</u>.

References

- 1. ^{(*}Immunization surveillance, assessment and monitoring", WHO <u>www.who.int/immunization_monitoring/diseases/tuberculosis/</u>
- 2. ↑ "BCG vaccine", WHO www.who.int/biologicals/areas/vaccines/

"Estimates of BCG coverage", WHO

- 3. ↑ //apps.who.int/immunization_monitoring/globalsummary/timeseries/tswucoveragebcg.ht ml
- 4. ↑ "The BCG World Atlas", <u>www.bcgatlas.org/index.php</u>
- 5. ↑ "Who should have the BCG (TB) vaccine?", NHS Choices, 2014, www.nhs.uk
- "Does my baby need the BCG vaccine against Tuberculosis?", The Portland Hospital, ¹ 2013, <u>www.theportlandhospital.com</u> 6.
- "When is the BCG (TB) vaccine needed? Vaccinations NHS Choices", NHS choices 7. ↑ www.cdc.gov/tb/topic/testing/
- 8. * BCG (tuberculosis) vaccination When it is needed", NHS Choices, www.nhs.uk/Conditions/BCG/Pages/When-it-is-needed.aspx
- "100,000 babies lose out due to lack of TB jab", Independent.ie, 9. 1 www.independent.ie/irish-news/health/
- 10 \uparrow BCG the current vaccine for tuberculosis, WHO www.who.int/vaccine_research/diseases/tb/vaccine_development
- "The Difference Between Latent TB Infection and Active TB Disease", CDC, 11 www.cdc.gov/TB/publications/factsheets/general/LTBIandActiveTB.htm
- ¹² ↑ "AERAS Global Efforts", AERAS <u>www.aeras.org/about-tb/global-efforts.php</u>
- , "Aera, GSK will test TB vaccine in India and Africa", Vaccine News Daily, October 12 13 ¹2012 <u>vaccinenewsdaily.com</u>
- "Safety and efficacy of MVA85A, a new tuberculosis vaccine, in infants previously
- ↑ vaccinated with BCG: a randomised, placebos-controlled phase 2B trials", The Lancet, February 4 2013 www.thelancet.com/
- 15 \uparrow "A major event for new tuberculosis vaccines", The Lancet, February 4 2013 www.thelancet.com/