

# New TB test means quicker and easier diagnosis for patients

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A new blood test could enable doctors to rule out tuberculosis (TB) infection within days rather than weeks, according to a new study published this week in the journal *Annals of Internal Medicine*.

The study, by researchers from Imperial College London and the University of Oxford, shows that doctors can determine that a patient does not have tuberculosis with 99% accuracy when using the new blood test, ELISpot-Plus, in conjunction with a skin test known as tuberculin skin testing, already in use.

TB is difficult to diagnose because many of its symptoms, such as fever, fatigue, and loss of appetite, are also commonly found in many other conditions. The combination of ELISpot-Plus and tuberculin skin testing is able to rule out TB within 48 hours, providing a much quicker result than existing testing methods, for which results take up to several weeks.

The new test combination could prevent patients who do not have TB from being subjected to further lengthy TB tests, and allow doctors to begin investigating other explanations for such patients' symptoms.

The new study showed that ELISpot-Plus alone was accurately able to determine TB infection in 89% of cases and tuberculin skin testing alone was able to determine TB infection in 79% of cases. However, using both tests together was able to rule out TB infection with an accuracy of 99%.

The ELISpot-Plus test works by detecting signs of a particular response that occurs when the immune system encounters TB infection. The test looks for a type of protein known as interferon- $\gamma$ . This is secreted by T cells in the immune system when they encounter antigens found in the bacterium *Mycobacterium tuberculosis*, which causes most cases of TB.

The tuberculin skin test commonly gives falsely positive results if a patient has previously been vaccinated against TB, because vaccination causes a reaction in the immune system which looks very similar to its reaction against actual TB infection. ELISpot-Plus is able to distinguish TB infection from BCG vaccination because it uses special antigens that only pick out the T cells that are induced by TB infection, and not those induced by vaccination.

The new test is useful in determining a patient's TB status but the results are not able to accurately reveal whether a patient with TB has it the 'active' form, which causes symptoms, or the dormant 'latent' form, which does not. This means that patients with a positive result would need further testing. However, the new test combination should allow doctors to establish which patients require further TB testing and which do not.

At present, the 'gold standard' for confirming whether or not a patient has TB involves growing cultures from sputum samples from a patient and analysing these cultures to see if they contain traces of *Mycobacterium tuberculosis*.

This means that patients being tested for TB need to stay in hospital for three days, undergoing invasive procedures, to obtain necessary samples. They then wait for several weeks for the results.

Professor Ajit Lalvani, from the National Heart and Lung Institute at Imperial College London, who led the study team, said: "Our new test could revolutionise the way we manage people with suspected TB. At the moment, it can take quite a long time to figure out whether or not a patient has the disease, because it can mimic many different conditions and present in many different ways.

"Our study shows that by using the new blood test, together with the old skin test, we could establish if someone does not have TB within two days of them

coming in for tests, allowing doctors to focus on other possible diagnoses. If we cannot rule out TB, we can then refer them for further testing to confirm the diagnosis. Using this new system would allow us to treat patients much more quickly and effectively," added Professor Lalvani.

The ELISpot-Plus device is not yet licensed and they intend to make it available to as large a number of TB patients as possible, including those in the developing world who carry the largest burden of TB, through ethical commercialisation.

The study looked at 389 patients recruited at Northwick Park Hospital in London and Heartlands Hospital in Birmingham. The researchers compared the performance of tuberculin skin testing and two blood tests, ELISpot and ELISpot-Plus, both individually and used in combination, in diagnosing patients with suspected active TB. The study was funded by the Wellcome Trust, the Sir Halley Stewart Trust and the UK Department of Health.

Britain is the only country in Western Europe where TB is on the rise and London, which carries almost half the national burden, is Europe's TB capital. Professor Lalvani leads a new, specially created TB Task Force at Imperial College London and its Academic Health Science Centre, Imperial College Healthcare NHS Trust. The TB Task Force aims to develop and deploy effective new weapons in the battle against TB, both in London and globally, through cutting-edge scientific research.

Professor Steve Smith, the Principal of the Faculty of Medicine at Imperial College London and Chief Executive of Imperial College Healthcare NHS Trust, said: "Our new Academic Health Science Centre integrates healthcare services with teaching and research to take the world's best research from bench to bedside - giving patients quicker access to new medical advances. We established Professor Lalvani's department because we value his patient-centred research and care deeply about London's growing TB problem. The work of Professor Lalvani and his team is an excellent example of world-class research providing significant benefits for our patients".

Source: Imperial College London

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