

Development of an alternative assay for tuberculin testing

Project team

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Project summary

Bovine PPD (purified protein derivatives) tuberculins are protein enriched, heat treated preparations of *Mycobacterium bovis* which are used to diagnose tuberculosis, which is an important zoonotic disease. The relevant, legally binding European Pharmacopoeia monograph currently stipulates skin testing of tuberculins in previously sensitized guinea pigs to assess batch potency. The test is based on a lengthy, distressful procedure of poor reproducibility.

In continuation of a preceding project, we are developing a functional assay, which no longer requires skin testing. Instead, mononuclear immune cells of immunized animals are stimulated *in vitro*. The reactivity of cells, i.e. their proliferation upon tuberculin stimulation determined by ELISA, will be correlated to tuberculin potency. In a second, fully animal-free approach, we aim to analyze the entire proteome of tuberculins by mass spectrometry in a cooperative project within PEI and with colleagues at the Friedrich-Loeffler-Institute. Suitable protein candidates will then be selected for exact quantification to assess the potency of tuberculin batches.

The final aim of the project is an adoption of the newly developed methods by the European Pharmacopoeia in order to attain wide spread use instead of the distressing tuberculin skin test in guinea pigs.

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Awards

- In 2016, Christina Spohr was awarded the Hessischer Tierschutz-Forschungspreis (Animal Protection Research Award from the Land [German Federal State] of Hesse) for developing a first blood cell-based testing method for tuberculins.