Field trial of an oral lipid-formulated BCG vaccine in wild badgers

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BACKGROUND

Eurasian badgers *(Meles meles*) are a maintenance host for *Mycobacterium bovis* and contribute to the spread and persistence of tuberculosis in cattle[1]. Options for control of *M.bovis* infection in badgers and prevention of spread of infection to cattle are limited, and include badger culling, badger vaccination and improved farm biosecurity. Badger removal operations, which reduce badger densities also result in reduced TB in associated cattle populations in ROI[1,3]. However, badgers are a protected species and badger removal is considered as an interim control strategy. There is a consensus that BCG vaccination offers a long-term sustainable solution and is key to solving the problem of *M.bovis* infection in badgers and cattle[2].

In studies with captive badgers the BCG vaccine, delivered by different routes, conferred significant levels of protection against experimental *M.bovis* challenge[4]. This large scale field trial is designed to test protection of the BCG vaccine in a wild badger population.

AIMS

1. To establish if a lipid-based oral BCG vaccine for *M.bovis* is protective in wild badgers.
2. To estimate vaccine efficacy.

METHODS

Study Design

Study Type: Randomised, double-blind, placebo-controlled field trial
Study Area: 755km^2, Co. Kilkenny
Badgers: TB endemic, est. population ~700
Duration: 4 years
Capture regime: Capture-tag-release. Capture at all setts twice/year for 3 yrs (Sep 2009 - Sep 2012)
Field data collection: Age, sex, weight, record of any injuries, GPS location of setts and blood collection.
Vaccine: Hand vaccinated - live oral BCG in lipid matrix or placebo, double-blind coded.
Vaccine deployment: Area divided into three zones (Zone 1, 2 and 3). Allocated 100%, 50%, 0% vaccination coverage (Fig. 1)

METHODS

Monitoring: Immuno-assays (serology)
Depopulation: Of trial badgers Sep 2012-Oct 2013.
Post mortem examination: Detailed (forensic) pm for gross lesions of tuberculosis. Multiple samples collected for histology and bacteriology.
Case definition: *M.bovis* positive by histology and/or bacteriology (Clinical samples or post mortem examination).

Analysis:

- Vaccine protection is measured as the proportion of infected badgers in vaccinated vs. control group.
- Vaccine efficacy is measured from the number of seropositive incident cases in the vaccinated vs. the control group.
- Only animals negative to serological tests on initial capture are included in the analysis.

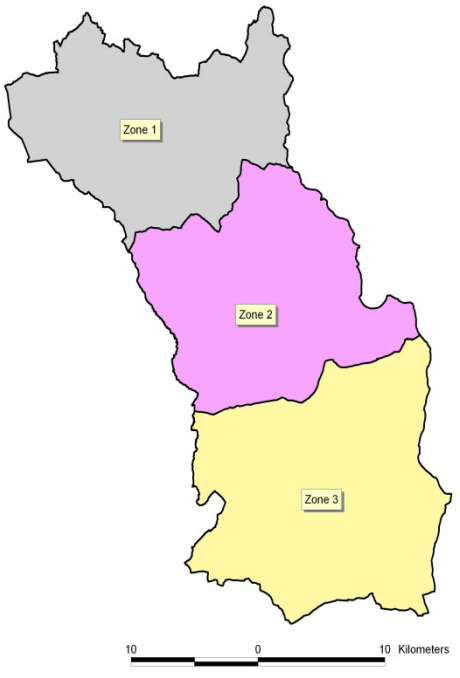

Fig. 1. Study area divided into three zones 1, 2 and 3 (grey, pink and yellow respectively). Zones received either 100%, 50% or 0% vaccination coverage.

RESULTS

Progress to date

Seven capture sweeps have been completed. During sweeps 1 to 6, 987 badgers were vaccinated with either BCG or placebo (Table 1). During the final sweep (Sweep 7), the trial site was depopulated and 273 badgers (Table 2) were removed and examined by post mortem.

Table 1

Treatment in the three zones of the field trial

Treatment	1*	2*	Total
Zone 1	0	369	369
Zone 2	115	114	229
Zone 3	388	1	389
Total	503	484	987

*Badgers receive either vaccine or placebo, blind coded 1 & 2

Table 2

Total no. of badgers removed during depopulation

Sweep 7	Total
Zone 1	118
Zone 2	68
Zone 3	87
Total	273

CONCLUSIONS

Confirmation of disease status of each trial badger is required for the accurate analysis of results.

The results and experience gained from the field trial will provide scientific support and facilitate the development of strategies for introduction of vaccination into the national bovine tuberculosis eradication scheme.

References

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