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Trial of the efficacy of a second dose of BCG vaccination against tuberculosis (Avaliação da eficácia da segunda dose da vacina BCG em escolares)

Submission date
17/01/2007

Recruitment status
No longer recruiting

Registration date
21/03/2007

Overall study status
Completed

Last Edited
15/03/2016

Condition category
Infections and Infestations

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The BCG vaccine protects against tuberculosis, a serious infection which affects the lungs. It has also been found to protect against leprosy, an infectious skin and nerve disease. The aim of this study is to assess the effectiveness of a second dose of BCG vaccination against tuberculosis and leprosy.

Who can participate?
Schoolchildren aged 7 to 14 years attending the participating state schools

What does the study involve?
Participating schools are randomly allocated to one of two groups: the intervention group and the control group. Participants in the intervention group schools receive a second BCG vaccination. Participants in the control group schools do not receive the second BCG vaccination. The number of cases of tuberculosis and leprosy are recorded in the two groups.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
767 state schools in the cities of Salvador and Manaus in Brazil

When is the study starting and how long is it expected to run for?
June 1996 to June 2016

Who is funding the study?
1. The Department For International Development (DFID) (UK)
2. Ministry of Health (Brazil)

Who is the main contact?
Prof. Mauricio Lima Barreto

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
R6715

Study information

Scientific Title
Trial of the efficacy of a second dose of BCG vaccination against tuberculosis (Avaliação da eficácia da segunda dose da vacina BCG em escolares)

Acronym
BCGREVAC

Study objectives
To estimate the efficacy of a second dose of BCG vaccination against tuberculosis and leprosy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Ethical Committee of the University Hospital Professor Edgard Santos (HUPES) of the Federal University of Bahia, 07/10/1996

2. National Committee for ethics in Research (Comitê Nacional de Etica em Pesquisa-CONEP), 30 /10/2003, judgement ref: 770/2003, submission ref: 250000.106515/2003-02

Study design
Cluster randomised trial, with schools being the unit of randomisation. There was no concealment of allocation or intervention and no placebo was used.

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
School

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Tuberculosis and leprosy

Interventions
The intervention was a single intradermal injection with BCG vaccine produced in Brazil using the Moreaux (Rio de Janeiro) strain. This will be a revaccination as children have a high coverage of BCG at birth. The control group will receive no vaccination.

The trial was conducted in two sites, the cities of Salvador and Manaus, in Brazil. Seven hundred and sixty seven state schools were included in the trial. Children in both treatment groups were visited at school to confirm their identification details and their arms were examined for BCG scars. Ascertainment of cases was through the tuberculosis control programme. Cases notified were reviewed independently by two chest physicians, who classified cases into confirmed (microbiological confirmation), probable (would treat based on the information from the records), suspected (no information in the record suggested this was not tuberculosis) and not tuberculosis (excluded from the analysis), and into pulmonary and non-pulmonary forms. A third specialist reviewed those classified differently by the two chest physicians. The validation was blind to vaccination.

Cases were linked to the study population in the study database. Linkage was done blind to vaccination status, based on the name of the child, the name of the mother, the sex and date of birth of the child. All possible matches were reviewed by a member of the study team to assess its reliability. Most were unique matches, with complete concordance on all variables. Home visits to a sample of cases not linked to the database identified only two cases (out of 144 visited) that belonged to the database.

Active informed consent was not obtained. This was because both intervention (BCG revaccination) and absence of intervention were in routine practice in different settings in Brazil

at the time, and therefore an "opt out" form of consent was deemed acceptable: parents of children in schools allocated to vaccination were given written information about the vaccine and the trial and offered the opportunity to withdraw their child from the trial.

Intervention Type
Biological/Vaccine

Primary outcome measure
1. Case of tuberculosis
2. Case of leprosy

Secondary outcome measures
1. Tuberculosis by form
2. Leprosy by form

Overall study start date
01/06/1996

Completion date
01/06/2016

Eligibility

Key inclusion criteria
School children aged 7 to 14 years in state schools

Participant type(s)
Other

Age group
Child

Lower age limit
7 Years

Upper age limit
14 Years

Sex
Both

Target number of participants
351,951

Key exclusion criteria
1. Children with special needs
2. Children who received more than one BCG vaccination

Date of first enrolment
01/06/1996

Date of final enrolment
01/06/2016

Locations

Countries of recruitment
Brazil

Study participating centre
Universidade Federal da Bahia
Salvador
Brazil
40.110-040

Sponsor information

Organisation
Institute for Collective Health (Instituto de Saúde Coletiva) (Brazil)

Sponsor details
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Sponsor type
University/education

Website
http://www.isc.ufba.br/isc.asp

ROR
https://ror.org/03k3p7647

Funder(s)

Funder type
Government

Funder Name
Department for International Development

Alternative Name(s)
Department for International Development, UK, DFID

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Ministry of Health (Brazil)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2001		Yes	No
Protocol article	protocol	01/10/2002		Yes	No
Results article	results	01/04/2003		Yes	No
Results article	results	01/04/2003		Yes	No
Protocol article	protocol	01/03/2004		Yes	No
Results article	results	01/12/2004		Yes	No
	results				

Results article		01/10/2005	Yes	No
Results article	results	08/10/2005	Yes	No
Results article	results	24/06/2014	Yes	No