

BCG Data Extraction Form: Baseline Data

Study_ID: 250007

Date extracted:		Reviewer:	
Ref ID:		Study Name:	
Author:		Year:	
Study IDs for additional extracted papers:		Study IDs for duplicates not extracted:	
Why was this publication selected for extraction?:			
Study Design:	Other		
Number of trial arms:		Comparator intervention:	
Comparator Details:			
Country:		City/Region:	
Recruitment Details:			
Year recruitment started:		Year recruitment ended:	
	<i>Source of population/Cases:</i>	<i>Source of preferred controls:</i>	<i>Source of other controls:</i>
General Population	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Outbreak	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Single hospital	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Multiple hospital	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
National Surveillance	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Local Surveillance	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Population subgroup	<input type="checkbox"/>		
Neighbourhood		<input type="checkbox"/>	<input type="checkbox"/>
Other	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Not specified	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Details of source pop (if not covered above):			
Were cases and control matched?:			
If yes, what factors were they matched on?			
Participant Details:			
Were patients with existing TB infection excluded at study start?			
Were patients with existing TB infection excluded at time of vaccination?			
In which groups were those with TB infection excluded?			
Was a tuberculin test part of the diagnostic procedures for cases?:			
Please list other inclusion criteria:			
<i>Age at vaccination</i>			
Mean:		Infant (<1 year)	<input type="checkbox"/>
Median:		Young childhood (1-5 years)	<input type="checkbox"/>
Range:		Older childhood (6-11 years)	<input type="checkbox"/>
		Teen (12-18 years)	<input type="checkbox"/>
		Adult (19+ years)	<input type="checkbox"/>
		All ages	<input type="checkbox"/>
Socioeconomic background:			

Background risk of disease in source population

Proportion Asian:
Proportion Black:
Proportion Hispanic:

Proportion Native American:
Proportion White:
No information on ethnicity provided

Other details of ethnicity:

Were any participants HIV infected?

Proportion infected:

Number in vaccinated group/cases at baseline:

Number in control group at baseline:

Vaccination Details

Were regional vaccine policies for vaccination period described?

What were the vaccination policies?

Reason for vaccination

Neonatal/Childhood vaccination
"Booster" vaccination
Occupational related
Research study related
Other
Not stated
Details, if other:

Vaccine strain

Connaught
Copenhagen
Danish (Statens)
Glaxo
Moreau (Brazilian)
Pasteur
Russian (Moscow)
Tice (BCG)
Tice (rBCG30)
Tkyo (Japanese)
Volebaccilus
Scphia (Bulgaria)
Madras
Coded by number only
Other
Not Stated

How was vaccination status ascertained?

Medical Records
Vaccinoin Card
Participant Recall
Parent of Participant Recall
BCG Scar
Other
Not stated

Vaccine strain number:

Details, if other:

Details, if other:

Year vaccination started:

Year vaccination ended:

Single or multi puncture?

Vaccine administration:

Reviewer comments:

BCG Data Extraction Form: Results

Result_ID: 250029

Study_ID: 250007

Date assessed: Reviewer:
Baseline Ref ID: Study Name:
Paper ref ID:

What sample do these data relate to?:

Sample details

Details same as previous forms with exception of completed fields

Age at vaccination:

Age at outcome assessment:

Years between vaccination and outcome:

Gender:

Duration of follow-up to determine outcome:

Outcome: Details, if other:

Was this outcome measured but results data were not available?

- How were cases identified at follow-up?
- Names matched to surveillance data
 - Names matched to mortality data
 - All participants were contacted
 - Medical Records
 - Hospital data
 - TB registries
 - Not stated
 - Queried at follow-up
 - Symptomatic participants assessed at follow-up
 - Morbidity reports
 - Medical records of all parts reviewed at follow-up
 - Other

Details, if other:

Case definition (include % for each subdefinition):

Were efforts made to determine what happened to those not cases?

VacUnvacc:

Were there any originally unvaccinated who subsequently were vaccinated?:

How was this handled in the study?

Control/Comparator Group:

Intervention arm:

Result Number:

2 x 2 Results:

	TB	No TB	Person years:
BCG	<input type="text"/>	<input type="text"/>	<input type="text"/>
Not vaccinated	<input type="text"/>	<input type="text"/>	<input type="text"/>

<i>Summary Results:</i>	<i>Effect measure</i>	<i>Adjusting details</i>	<i>Result</i>	<i>95% CI</i>
Crude:	<input type="text"/>		<input type="text" value="0"/>	<input type="text" value="0"/>
Age and sex adjusted:	<input type="text"/>	<input type="text"/>	<input type="text" value="0"/>	<input type="text" value="0"/>
Fully adjusted:	<input type="text"/>	<input type="text"/>	<input type="text" value="0"/>	<input type="text" value="0"/>

Factors adjusted for in fully adjusted model:

If the controls were matched to cases, were matched analyses conducted?:

Response rate for cases (%):

Response rate for controls (%):

Reviewer comments:

BCG Quality Assessment Form : RCTs

Study_ID:

250008

Ref ID:

Study Name:

Author:

Reviewer:

1. Randomisation

Method for generating randomization sequence:

Randomisation method

Was the allocation sequence adequately generated?

2. Concealment of treatment allocation

Method for concealing treatment allocation

Was allocation adequately concealed?

3. Withdrawals

% drop-outs in the BCG group:

% drop-outs in the non-vaccinated group:

Were reasons for withdrawals similar across groups?

Were reasons for withdrawals related to the outcome?

IF YES TO ABOVE, give details

Were appropriate methods used to impute missing data?:

Was an intention-to-treat analysis conducted?

Were incomplete outcome data adequately addressed?

4. Blinding

Were outcome assessors blinded?

Were participants blinded?

Were vaccine administrators blinded?

Was knowledge of the allocated intervention prevented during the study

5. Selective outcome reporting

Were data reported for all pre-specified outcomes?:

Were data reported for all pre-specified sub-group analyses?

Are reports of the study free of suggestion of selective outcome reporting?

6. Case ascertainment

Were methods of ascertainment of cases identical for vaccinated and unvaccinated groups?

Was ascertainment of cases complete?

Notes:

BCG Quality Assessment Form : Other study designs

Study_ID:

250009

Ref ID:

Study Name:

Author:

1. Cohort studies

Supporting data

Rating

Was follow-up independent of vaccination status?:

Was case ascertainment blinded to vaccination status?

Were methods of ascertainment of cases identical for vaccinated and unvaccinated groups?

Were data reported for all pre-specified sub-group analyses?

Were incomplete outcome data adequately addressed?:

% withdrawals in BCG group:

% withdrawals in non-vaccinated group:

Were reasons for withdrawals similar across groups?:

Were reasons for withdrawals related to outcome

Were missing data imputed using appropriate methods?:

Was an intention to treat analysis conducted?:

2. Cross-sectional and case-control studies

Were vaccination definitions the same for everyone (cases and controls) in the study?:

Was disease status blinded to BCG assessors?

Were controls selected from the same population as the cases? (CC only)

Were cases and controls ascertained independent of vaccine status?:

3. Case population studies

Were cases and population the same?

In terms of geography?

In terms of time?

In terms of age?

Notes:

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