

The Calmette Study

Randomised clinical trial of the BCG vaccine

Lone Graff Stensballe, pediatrician, PhD, research leader

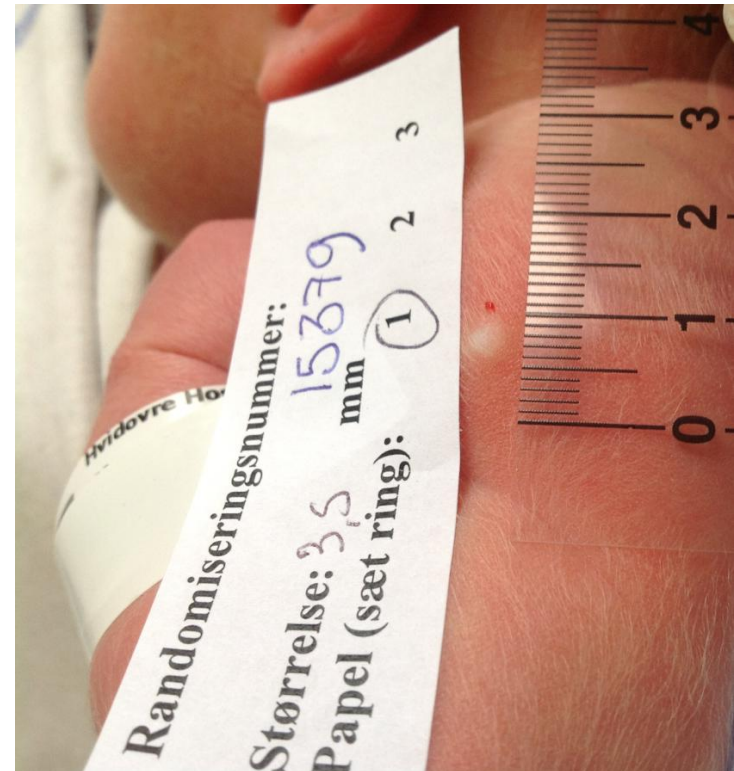


Bacille Calmette Guérin Immunisation at Birth and Childhood Morbidity in Danish Children

- 4300 newborns
 - Follow-up at age 3 and 13 months
- Test the hypothesis that infants who get the BCG vaccine at birth experience 20% fewer hospitalisations during early childhood
- Morbidity
 - Infections
 - Atopic disease: Eczema, asthma, allergy
- Growth and development
- Immunology
 - Blood

Agenda

- Screening and inclusion
- Adverse events
- Follow-up adherence
 - The preliminary results of two sub-studies



Inclusion, Oct 2012– Nov 2013

Location	Study base	Randomised births (% study base)	Premature births
Hvidovre	7201	1450 (20%)	26
Kolding	3310	1202 (36%)	38
Rigshospitalet	6106	1533 (25%)	59
Total		4185	123
Total newborns		4262	

Normal reactions



Adverse events (preliminary)

Randomisation	Adverse event	Related adverse event	Severe adverse event	Related severe adverse event
BCG	135	83	58	2
No intervention	117	0	44	0

Side effects



Side effects





ELSEVIER

Contents lists available at [ScienceDirect](#)

Vaccine

journal homepage: www.elsevier.com/locate/vaccine

Investigations into an outbreak of suppurative lymphadenitis with BCG vaccine SSI[®] in Singapore

Sally Bee Leng Soh^{a,*}, Phey Yen Han^a, Kai Tong Tam^a, Chee Fu Yung^b, Woei Kang Liew^c, Natalie Woon Hui Tan^{c,d,e}, Chia Yin Chong^{c,d,e}, Koh Cheng Thoon^{c,d,e}

- Batch-to-batch variation
- 2011 spike in the incidence rate of suppurative lymphadenitis, 3.16 per 1000 vaccinées, *versus* 0.71 to 0.85 in 2009, 2011 and 2012



3-months follow-up



Location	Interview	Clinical examination
Hvidovre	97%	91%
Kolding	99%	97%
Rigshospitalet	98%	98%
Total	98%	94%

13-months follow-up

Location	1st birthday	Interview	Clinical examination	ASQ
Hvidovre	1290	1250	1046	997
Kolding	1043	1037	949	861
Rigshospitalet	1373	1348	1265	1237
Total	3706 (87%)	3635 (98%)	3260 (88%)	3095 (84%)

WE DELIVER THE IMPOSSIBLE IN A TIMELY MANNER



How do we manage?

- Very dedicated staff
 - Midwives
 - Nurses
 - PhD-students
 - Scholarships
- Very dedicated participants



RESEARCH

Open Access

Disappointment and adherence among parents of newborns allocated to the control group: a qualitative study of a randomized clinical trial

Sandra Meinich Petersen^{1*}, Vibeke Zoffmann^{2,3}, Jesper Kjærgaard¹, Lone Graff Steensballe⁴ and Gorm Greisen¹

- Disappointment among parents randomised to the control group
- Support the parents motives for participation

Obtaining informed consent per telephone

A randomised controlled trial

Foss K, Kjaergaard J, Stensballe LG, Greisen G

- Inclusion face-to-face *versus* per telephone
- Primary outcome: Total score of knowledge and satisfaction
- Higher total score in face-to-face group ($p < 0.001$)
- Due to difference in satisfaction ($p < 0.001$)
 - High satisfaction in both groups
- No difference in knowledge
- Less use of time (8.9 vs. 12.1 minutes), and resources





DO YOU KNOW WHAT YOU ARE DOING?