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BCG trial 2012-2013 in 4262 Danish newborns to study potential non-specific effects: Results and adverse events

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Background: The Bacillus Calmette-Guérin (BCG) vaccine is administered to protect against tuberculosis, but studies from low-income countries suggest that there may also be non-specific beneficial effects upon the infant immune system, reducing early non-targeted infections and atopic diseases. The Danish Calmette Study, a large-scale randomised single-blind trial in Denmark to test the effect of BCG given at birth on childhood morbidity, including hospitalisation, infections, atopic disease, growth, development and immunological indicators; the primary outcome being all-cause hospitalisations analysed as repeated events from birth to 15 months of age. The rate of adverse events was registered.

Methods: Pregnant women planning to give birth at three Danish hospitals were invited to participate. After parental consent, newborn children were allocated to BCG or no intervention within 7 days of age. Randomisation was stratified by prematurity. Hospitalisations were identified using The Danish National Patient Register. Primary outcome data were analysed by Cox proportional hazard models in intention-to-treat and per-protocol analyses according to the statistical analysis plan deposited at the Data Safety Monitoring Board before data was un-blinded.

Results: 4184 pregnant women were randomised and their 4262 children allocated to BCG or no intervention. There was no difference in risk of hospitalisation up to 15 months of age. In primary analyses of secondary outcomes, no significant effect of BCG have been identified. The rate of local reactions and suppurative lymphadenitis was fivefold of what was expected.

Conclusion: In affluent countries, BCG at birth is not likely to have a major impact on common illness in infancy.

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The controversial second impact syndrome: A review of the literature

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Second impact syndrome is a devastating injury that primarily affects athletic children and young adults. It occurs when a second concussion occurs before symptoms from the first concussion have resolved. Diffuse and often catastrophic cerebral edema results. Reports of second impact syndrome are few, and some argue that second impact syndrome is simply diffuse cerebral swelling unrelated to the first concussion. Ovid and PubMed were searched from years 1946 to 2015 using the terms "second impact syndrome", "repeat concussion", and "catastrophic brain injury". To broaden the search, review articles were found using a combination of the terms, "concussion", "second impact syndrome", and "repetitive head trauma". 17 patients in seven publications met the criteria of having two witnessed hits and persistent and unresolved symptoms from the first to the second concussion. 10 of the seventeen (59%) included individuals were football players. All were male. Ages ranged from 13 to 23 years. All patients who had poor outcomes (death or permanent disability) were younger than 20 years. Conversely, 4 of the five players with good outcomes were older than 19 years. The lag time from first to second concussion ranged from one hour to four weeks, and in many cases, at least one of the two hits appeared minor. American football, male gender, and young age appear to be associated with second impact syndrome. Controversies surrounding this syndrome are discussed. There is a need for prospective studies to clarify risk factors and outcomes of second impact syndrome to guide return-to-play recommendations for young athletes.

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