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| --- | --- | --- | --- | --- | --- | --- | --- |
| **Study number** | **Objective(s) of the Study** | **Test Product(s): Dosage Regimen; Route of Administration** | **Number of Subjects** | **target populaton** | **Duration of Treatment** | **Study Status** | **Study period** |
| 38-93-011 | Safety & Immunogenicity  of Sci‑B-Vac & Engerix B | Sci-B-Vac  Single Dose,  IM, 2.5 mcg  Comparator: Engerix B 10mcg | 205  (153 in Sci-B-Vac arm) | Healthy Neonates | Injection at birth, day 30 & 180; Follow up to 1 year | Completed | 01/1994-07/1995 |
| 38-98-060 | Safety & Immunogenicity of Sci‑B-Vac Vs. Engerix-B | Sci-B-Vac  Single dose,  IM, 2.5 mcg  Comparator:  Engerix B 10 mcg | 206  (139 in Sci-B-Vac arm) | Healthy Neonates | Injection at birth, day 30 & 180; Follow up to 1 year | Completed | 08/1998-03/2001 |
| 38-01-070 | Immunogenicity of mixed regimen of Sci‑B-Vac and Engerix B. | Single dose  IM, Sci-B-Vac 2.5 mcg  Comparator: Engerix B 10 mcg | 70 | Healthy Neonates | Injection at birth, day 30 & 180; Follow up to 7 months | Completed | 07/2001-03/2002 |
| 38-92-005 | Safety & Immunogenicity of Sci-B-Vac | Sci-B-Vac  Single dose,  IM, 2.5 or 5mcg | 200 | Healthy Neonates | Injection within 48 hours of birth, day 30 & 180;  Follow up to 1 year | Completed | 02/1995-10/1996 |
| HBN 014-01-1 | Safety & Immunogenicity of Sci‑B-Vac | Sci-B-Vac  Single Dose,  IM, 2.5 mcg | 495 | Healthy Neonates with or without High Risk | Injection at birth, day 30 & 180; Follow up to 1 year | Completed | 06/1992-12/1994 |
| HBN 014-01-2 | Safety & Immunogenicity of Sci‑B‑Vac | Sci-B-Vac  Single dose,  IM, 5.0 mcg | 200 | Healthy Neonates with or without High Risk | Injection at birth, day 30 & 180; Follow up to 1 year | Completed | 08/1994-06/1996 |
| HBN-002-01 | Safety & Immunogenicity of Sci-B-Vac | Sci-B-Vac  Single dose,  IM, 2.5 or 5 mcg | 151 | Healthy Neonates with or without High Risk | Injection at birth, day 30 & 180; Follow up to 1 year | Completed | 02/1992-07/1996 |
| HBN 018-01 | Safety & Immunogenicity of Sci-B-Vac | Sci-B-Vac  Single Dose,  IM. 2.5 or 5mcg | 160 | Healthy Neonates with High Risk | Injection at birth, day 30 & 180; Follow up to 1 year | Completed | 09/1993-12/1995 |

**Tabulated list of clinical studies conducted in neonates**