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Effect of needle size on serum antibody responses and incidence of general reactions following routine immunisations in infants

Submission date
23/01/2004

Recruitment status
No longer recruiting

Registration date
23/01/2004

Overall study status
Completed

Last Edited
22/02/2008

Condition category
Infections and Infestations

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
SEO232

Study information

Scientific Title

Study objectives
When giving routine immunisations to infants, does the needle size used to administer the vaccines affect the serum antibody responses and/or the incidence of local and general reactions.

Ethics approval required
Old ethics approval format

Ethics approval(s)
This study was approved by the Mid and South Buckinghamshire and Oxfordshire local research ethics committees.

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Vaccination

Interventions
1. 23 gauge 25 mm - wider gauge long needle
2. 25 gauge 16 mm - narrower gauge short needle
3. 25 gauge 25 mm - narrower gauge long needle

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
1. Comparison of geometric mean titres of Diphtheria/Tetanus and Hib antibodies between needle size groups
2. Comparison of incidence of general and local reactions between needle size groups at three time points - following vaccination at two, three and four months

Key secondary outcome(s)
Not provided at time of registration

Completion date
20/06/2003

Eligibility

Key inclusion criteria
Healthy infants attending routine immunisation clinics at eight general practices.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Sex
All

Key exclusion criteria
1. Infants with severe chronic disease
2. Infants who may receive treatment likely to alter the immune response or infants with any conditions which could preclude evaluation of the response, e.g. congenital or acquired immunodeficiency
3. Infants who have already received Diphtheria-Tetanus-Pertussis (DPT)/Hib vaccines

Date of first enrolment
20/01/2002

Date of final enrolment
20/06/2003

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Oxford Vaccine Group
Oxford
United Kingdom
OX3 9DU

Sponsor information

Organisation
NHS R&D Regional Programme Register - Department of Health (UK)

Funder(s)

Funder type
Government

Funder Name
NHS Executive South East (UK)

Results and Publications

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	16/09/2006		Yes	No