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

Submission date	Recruitment status	Prospectively registered		
23/01/2004	No longer recruiting	☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
23/01/2004	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
22/02/2008	Infections and Infestations			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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.

Study design

Randomised controlled trial

Primary study design

Interventional

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