ISRCTN62032215 https://doi.org/10.1186/ISRCTN62032215

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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 23/01/2004	**Overall study status** Completed	
Last Edited 22/02/2008	**Condition category** Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mrs Linda Diggle

Contact details
Oxford Vaccine Group
Room 4250, Level 4
University Department of Paediatrics
John Radclifffe Hospital
Oxford
United Kingdom
OX3 9DU
+44 01865 221229
linda.diggle@paediatrics.ox.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
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

Secondary outcome measures
Not provided at time of registration

Overall study start date
20/01/2002

Completion date
20/06/2003

Eligibility

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

Participant type(s)
Patient

Age group
Child

Sex
Both

Target number of participants
696

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
England

United Kingdom

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

Sponsor information

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

Sponsor details
The Department of Health
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
NHS Executive South East (UK)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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