ISRCTN15762138 https://doi.org/10.1186/ISRCTN15762138

Vaccination Response in Immuno-Compromised Host 2

Submission date	Recruitment status	[_] Prospectively registered
20/12/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
20/12/2005	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
14/11/2008	Infections and Infestations	[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr L.B.S. Gelinck

Contact details
Leiden University Medical Centre (LUMC)
P.O. Box 9600
Leiden
Netherlands
2300 RC
+31 (0)71 526 9111
L.B.S.Gelinck@LUMC.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
p05.115; NTR273

Study information

Scientific Title
Comparison of antibody response upon influenza vaccination after intradermal versus intramuscular injection in immunocompromised hosts

Acronym
RICH 2

Study objectives
Intradermal vaccination with one fifth of the total vaccine dose intradermally is just as efficient as intramuscular vaccination with the regular dose.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from the local medical ethics committee

Study design
Multicentre, randomised, active controlled, parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Influenza vaccination response

Interventions
1. Intradermal vaccination
2. Intramuscular vaccination

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)

Influenza vaccination

Primary outcome measure
Geometric mean titre (GMT) 30 days post-vaccination

Secondary outcome measures
Protection rates

Overall study start date
04/10/2005

Completion date
01/04/2006

Eligibility

Key inclusion criteria
Immunocompromised patients at least 18 years of age.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
580

Key exclusion criteria
1. Active infection
2. Pregnancy
3. Life expectancy of less than 6 months
4. Thrombocytopenia
5. Coumarin therapy
6. Thin skin with steroids
7. Known allergies
8. Influenza vaccination within last 9 months

Date of first enrolment
04/10/2005

Date of final enrolment
01/04/2006

Locations

Countries of recruitment
Netherlands

Study participating centre
Leiden University Medical Centre (LUMC)
Leiden
Netherlands
2300 RC

Sponsor information

Organisation
Leiden University Medical Centre (LUMC) (Netherlands)

Sponsor details
Albinusdreef 2
P.O. Box 9600
Leiden
Netherlands
2300 RC

Sponsor type
University/education

Website
http://www.lumc.nl/

ROR
https://ror.org/027bh9e22

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Leiden University Medical Centre (LUMC) (The Netherlands)

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