

Vaccination Response in Immuno-Compromised Host 2

Submission date 20/12/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 20/12/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 14/11/2008	Condition category Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

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
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

Primary study design

Interventional

Study design

Multicentre, randomised, active controlled, parallel group trial

Study type(s)

Treatment

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(s)

Geometric mean titre (GMT) 30 days post-vaccination

Key secondary outcome(s)

Protection rates

Completion date

01/04/2006

Eligibility**Key inclusion criteria**

Immunocompromised patients at least 18 years of age.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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)

ROR

<https://ror.org/027bh9e22>

Funder(s)**Funder type**

Hospital/treatment centre

Funder Name

Leiden University Medical Centre (LUMC) (The Netherlands)

Results and Publications**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration