

Intradermal Hepatitis-B-vaccination in non-responders after application of imiquimod 5% at the site of vaccination.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24074

Source

Nationaal Trial Register

Brief title

N/A

Health condition

non-responsiveness to hepatitis B vaccination (with recombinant vaccine).

Sponsors and support

Primary sponsor: A.H.E. Roukens, MD

L.G. Visser, MD, PhD

Source(s) of monetary or material Support: Dept. of Infectious Diseases, Leiden University Medical Center (LUMC)

Intervention

Outcome measures

Primary outcome

Serologic response after vaccination

Secondary outcome

Adverse events
Cellular immunity

Study description

Background summary

In this trial we investigate whether intradermal Hepatitis B vaccination in previously non-responders elicit an antibody response after application of imiquimod 5% at the site of vaccination.

Study objective

Imiquimod stimulates dendritic cell antigen presentation and migration to lymphnodes. Since dendritic cells are present in the dermis and epidermis, vaccination in the dermis could target these cells and, with simultaneous topical imiquimod treatment elicit an immune response in previously non-responders to hepatitis B vaccination.

Intervention

Intradermal hepatitis B vaccination with recombinant vaccine after topical treatment with imiquimod 5% cream

Contacts

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Eligibility criteria

Inclusion criteria

1. >18 yrs;
2. Minimal 2 series of Hepatitis B vaccination (= minimal 6 intramuscular injections of 10microgr recombinant hepatitis B vaccine) with antibody titre <10IU/ml.

Exclusion criteria

1. Carrier of hepatitis B virus;
2. Known immunosuppressive state due to illness or medication;
3. Autoimmune disorder;
4. Pregnancy.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Open (masking not used)
Control:	Placebo

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-05-2007
Enrollment:	26
Type:	Anticipated

Ethics review

Positive opinion

Date: 31-08-2007

Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL1014
NTR-old	NTR1043
Other	: Wordt nog doorgegeven
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results