Influenza trial.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON21325

Source
NTR

Brief title
Influenza trial

Health condition

RA, reuma, Rheumatoid Arthritis

Sponsors and support

Primary sponsor: Academisch Medisch Centrum, div Immunology and Rheumatology
Source(s) of monetary or material Support: Academisch Medisch Centrum, div Immunology and Rheumatology

Intervention

Outcome measures

Primary outcome

1. Frequency of in-vitro responding clones during follow-up of the new influenza A/H1N1 virus infection;

2. Functional characterization of individual responding clones;

3. Correlation of T-cell responses with antibody responses.

Secondary outcome

Antibody titers of 1:40 or more on hemagglutination-inhibition (HI) assay to quantify the presence of specific antigens.

Study description

Background summary

Country of recruitment: the Netherlands.

We want to study otherwise healthy volunteers undergoing new influenza A/H1N1 infection.

We will combine in-vitro stimulation assays and High Throughput Sequencing to identify, quantify and phenotype the clones that play a functional role in influenza infections and follow them over time.

Study objective

Gaining knowledge on human responses against the influenza virus will help us in treating influenza infections and lead to
more effective vaccines. Additionally, it might also lead to identification of individuals that have a high risk of morbidity and even mortality during infection.

Study design

Day 0-4, 7, 14, 28, 56, 84, 112 and 140.

Intervention

We want to study otherwise healthy volunteers undergoing new influenza A/H1N1 infection.

We will combine in-vitro stimulation assays and High Throughput Sequencing to identify, quantify and phenotype the clones that play a functional role in influenza infections and follow them over time.

Contacts

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Eligibility criteria

Inclusion criteria

1. Able and willing to give written informed consent;

2. Age 18-85 years;

3. PCR-confirmed new influenza A/H1N1 infection with symptoms present for less than 4 days.

Exclusion criteria

1. Therapy within the previous 60 days with:

A. Any experimental drug;

B. Monoclonal antibodies;

C. Growth factors;

D. Other anti-cytokines.

2. Therapy within the previous 28 days with:

A. Anti-viral medication;

B. Parenteral corticoid injections;

C. Oral corticosteroid therapy exceeding a prednisone equivalent of 10 mg daily.

3. Any clinically significant medical condition;

4. Mental condition rendering the patient unable to understand the nature, scope and possible consequences of the study and/or evidence of an uncooperative attitude.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-04-2010
Enrollment:	10
Type:	Anticipated

Ethics review

Positive opinion

Date:	02-08-2010
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	NL2352
NTR-old	NTR2459
Other	MEC AMC : 10/084
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A