

Influenza trial.

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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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON21325

Bron

NTR

Verkorte titel

Influenza trial

Aandoening

RA, reuma, Rheumatoid Arthritis

Ondersteuning

Primaire sponsor: Academisch Medisch Centrum, div Immunology and Rheumatology

Overige ondersteuning: Academisch Medisch Centrum, div Immunology and Rheumatology

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-04-2010
Aantal proefpersonen:	10
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	02-08-2010
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2352
NTR-old	NTR2459
Ander register	MEC AMC : 10/084
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A