Nailfold videocapillaroscopy in juvenile (systemic) autoimmune diseases

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1. to describe NVC findings in patients with pediatric (systemic) auto-immune/-inflammatory diseases:- Juvenile systemic/localized sclerosis (jSSc/lSc)- Childhood-onset systemic lupus erythematosus (cSLE)- Juvenile dermatomyositis (JDM)- Juvenile...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Autoimmune disorders
Study type	Observational non invasive

Summary

ID

NL-OMON50708

Source
ToetsingOnline

Brief title
Capillaroscopy in juvenile autoimmunity

Condition

- Autoimmune disorders
- Joint disorders
- Vascular disorders NEC

Synonym
autoimmunity, lupus, Raynaud

Research involving
Human

Sponsors and support

Primary sponsor: Emma Kinderziekenhuis
Source(s) of monetary or material Support: Sichting Steun Emma: bedrag toegekend voor pilot. Aanvraag bij reumafonds volgt mogelijk nog in de nabije toekomst

Intervention

Keyword: Autoimmunity, Juvenile, Vasculopathy, Videocapillaroscopy

Outcome measures

Primary outcome

NVC measurements consist of describing the following variables per 1 mm image

(4 images per finger, digits 2-5 on both sides):

- Density: number of capillaries per mm (mean 9, range 6-12)

- Abnormal shapes described as not-hairpin/tortuous/crossing (1)

- Capillary apex maximum diameter (20-50 mcm described as enlarged, >50mcm

described as giant capillary)

- Large micro-hemorrhages (pathological bleedings with apical cap-like

appearance)

- Small multiple point-shaped hemorrhages surrounding the capillary loop

(extravasations)

Specific endpoint for study 3: diagnosis of a (systemic) autoimmune disease.

Secondary outcome

not applicable

Study description

Background summary

Nail fold video-capillaroscopy (NVC) is a non-invasive, easy-to-perform magnification method to visualize the capillary bed of the fingertips. It is used in adults with Raynaud*s phenomenon as a diagnostic tool for the presence of vasculopathy which is correlated with the risk of development of systemic

sclerosis (SSc). Classification of NVC-findings in adults with SSc also seem to correlate with severity of organ involvement. However, in children data on capillaroscopy are scarce.

Study objective

1. to describe NVC findings in patients with pediatric (systemic) auto-immune/-inflammatory diseases:
- Juvenile systemic/localized sclerosis (jSSc/lSc)
- Childhood-onset systemic lupus erythematosus (cSLE)
- Juvenile dermatomyositis (JDM)
- Juvenile idiopathic arthritis (JIA)
- Kawasaki disease (KD)
- Raynaud*s phenomenon (RP)

and compare them with NVC findings in healthy children (participants in the sub-study *Nailfold capillaroscopy in pediatric rheumatic diseases and healthy children*)

2. to establish classification criteria for abnormal NVC findings in patients with cSLE

3. to assess if this classification of NVC findings in cSLE:
- is associated with disease activity
- is associated with the type of organ involvement and with future disease activity/-organ involvement
- can be changed due to medication effects

4. to assess the risk for developing a systemic auto-immune disease in patients with abnormal NVC findings and Raynaud*s phenomenon with a pediatric onset

Study design

Part 1. Observational cross-sectional international study in healthy children and pediatric patients with (systemic) autoimmune/-inflammatory diseases: SSc, lSc, SLE, JDM, RP, JIA, KD and RP

This sub-study is a part of the international multicenter cross-sectional study *Nail fold capillaroscopy in pediatric rheumatic diseases and healthy children*, Belgian registration number B670201627545)

Capillaroscopy: once

Part 2. Prospective international multicenter cohort study in children and young adults with cSLE

Capillaroscopy: t=0, t=6 months and then yearly for 5 years (+optional 5 years)

Part 3. Prospective international multicenter cohort study in children and young adults with RP

Capillaroscopy: t=0 and then yearly for 5 years (+optional 5 years)

Study burden and risks

NVC is a non-invasive, non-painful method to visualize the smallest blood vessels in the nail fold area of the fingertips. It is already part of standard clinical care in systemic autoimmune diseases for diagnostic purpose. The patient is in a sitting position at a table and does not need to remove any clothing. There is no risk and negligible burden for the participant.

A possible burden for some, namely cSLE- and RP-patients, consists of extra blood sampling of 10-15 ml blood, which will only be taken if a venipuncture is part of standard clinical care. If there is a request for blood sampling as part of standard care, the 10-15 ml will be additional. This means no additional venipuncture will be necessary and therefore minimally invasive.

Contacts

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Scientific
Selecteer

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

1. Healthy children, 6-18 years old2. Pediatric patients < 18 years old, with one of the following diagnoses:
- Systemic lupus erythematosus (SLE), according to Systemic Lupus International Collaborating Clinics (SLICC) criteria
- Systemic sclerosis (SSc), according to EULAR criteria
- lokalized scleroderma (lSc), differentiated from SSc by the absence of sclerodactyly, RP, nailfold capillary changes, and organ involvement
- Juvenile dermatomyositis (JDM), according to Bohan and Peter criteria
- Juvenile idiopathic arthritis (JIA), according to the International League of Associations for Rheumatology (ILAR) criteria
- Kawasaki disease (KD), according to the 5th revision of diagnostic criteria
- Raynaud's phenomenon (RP), diagnostic questions as described by Wigley3. Adult patients >=18 years old, with a diagnosis childhood-onset SLE / RP, diagnosed before the age of 18#*¶*l/+

Exclusion criteria

Lack of written informed consent

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	22-10-2017
Enrollment:	400
Type:	Actual

Ethics review

Approved WMO Date:	16-10-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	01-11-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-11-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
CCMO	NL60885.018.17