PRACTOPICS 29 jan 2021

Sint-Augustinus
GZA . Ziekenhuizen

Reumatologie

De Bock Wouter
De Clercq Luc
De Knop Kathleen
Hoffman Ilse
Vos Ine

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De rol van capillaroscopie

Vos Ine

CASUS

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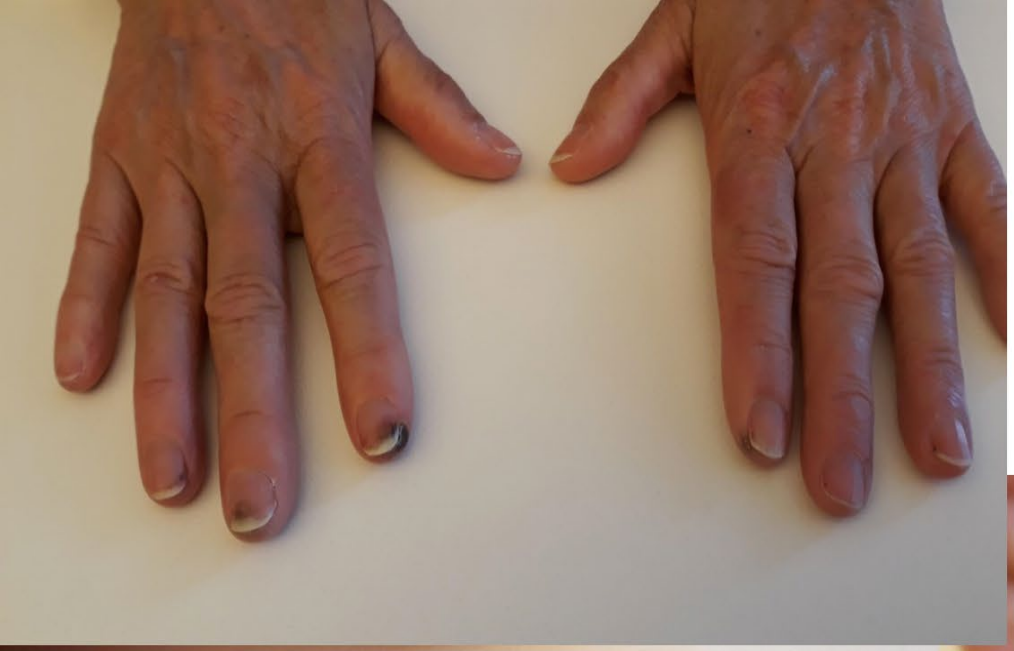
Voorgeschiedenis

- 06/2017: recent raynaud, ANF positief 1/1280 met anti-Centromeer
- 10/2017: synovitiden polsen en MCP gewrichten, RF positief: RA beeld. Opstarten MTX. Nadien plaquenil toegevoegd
- 11/2019: toename raynaud fenomeen, geen synovitis: toevoegen nifedipine
- 02/2020: nifedipine -> vochtretentie, nadien lercanidipine -> idem Raynaud thv handen. Capillaroscopie te plannen

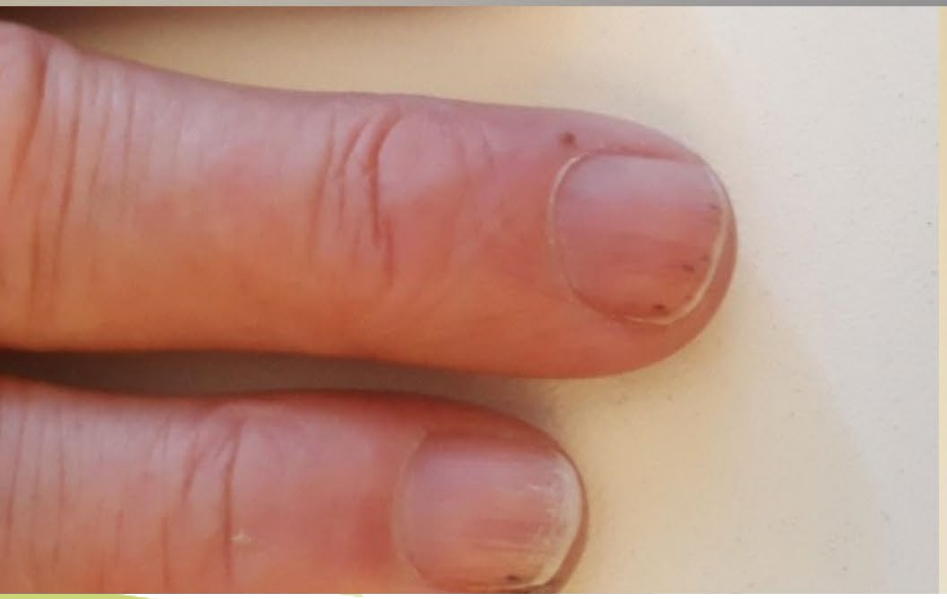
Huidige problematiek

- 05/2020: opname gastro-enterologie omwille van
- Sinds een 4-tal weken jeuk
- Vermagering van 3 kg over enkele weken
- 14 dagen geleden pijnklachten en donkere verkleuring van vingertoppen straal 2,3 rechts
- Laatste 2 dagen pijn en verkleuring thv vingertop 2 links. Zwarte verkleuring en uitbreiding naar proximaal straal 2 rechts



Klinisch onderzoek

- Vingertopnecrose 2 en 3 re, 2 li
- Splinterbloedingen straal 3 li
- Geen sklerodactylie



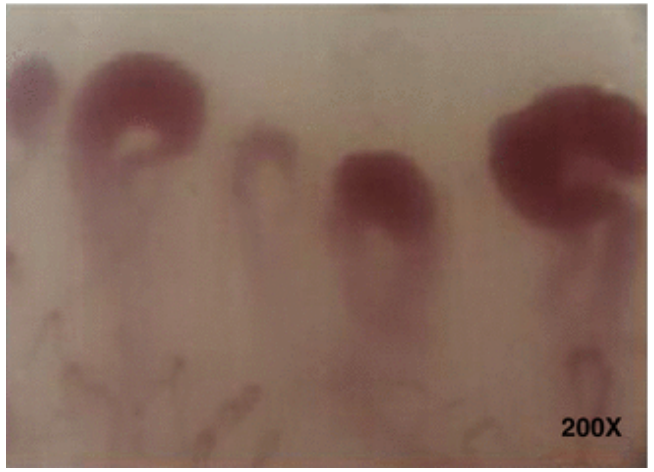
Investigaties

- Labo: ANF + 1/640, anti-centromeer patroon, CENP-B +++ anti-SSA/Ro60 +++ SSB+++, anti-fosfolipiden antistoffen negatief

- Capillaroscopie:

  Scleroderma patroon

  → giants (>90µm)



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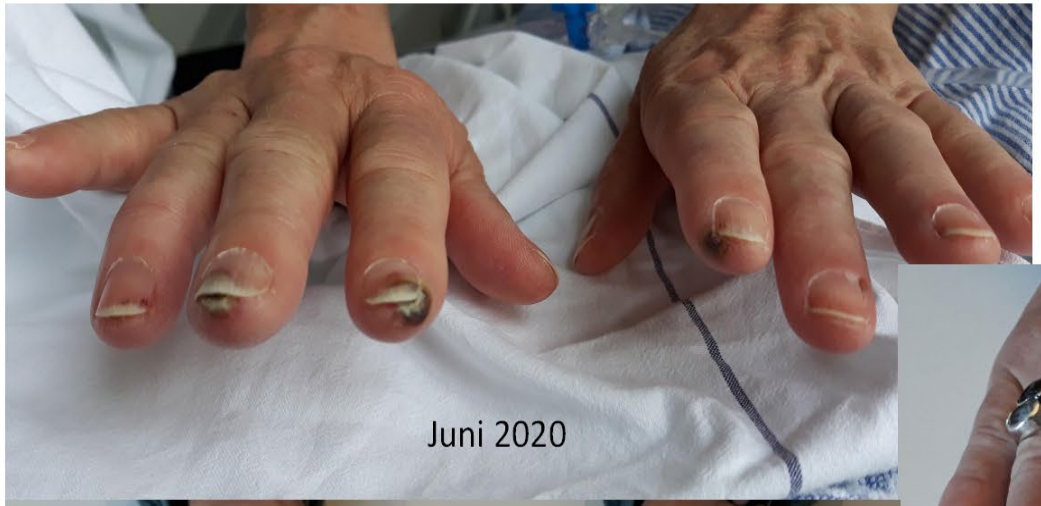
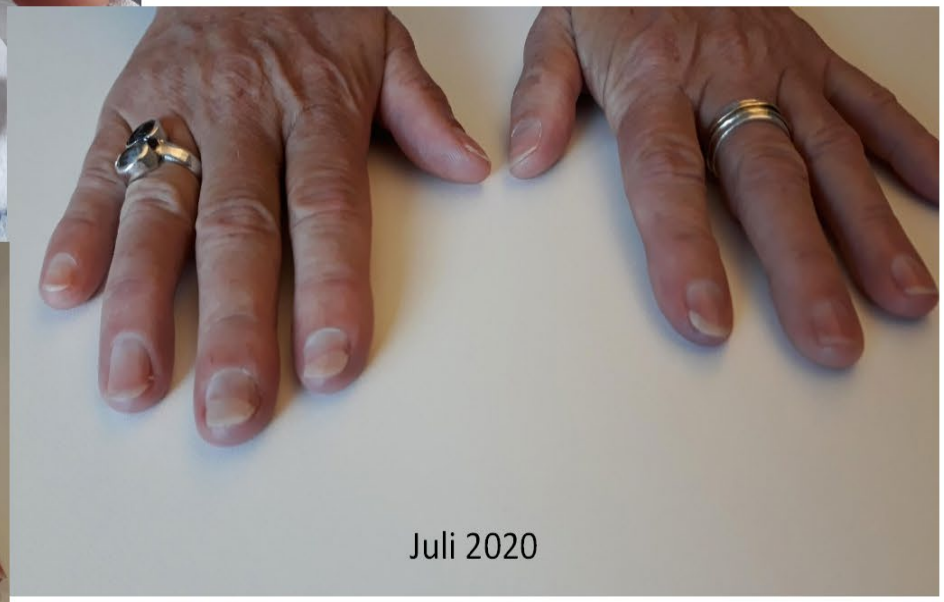
Diagnose

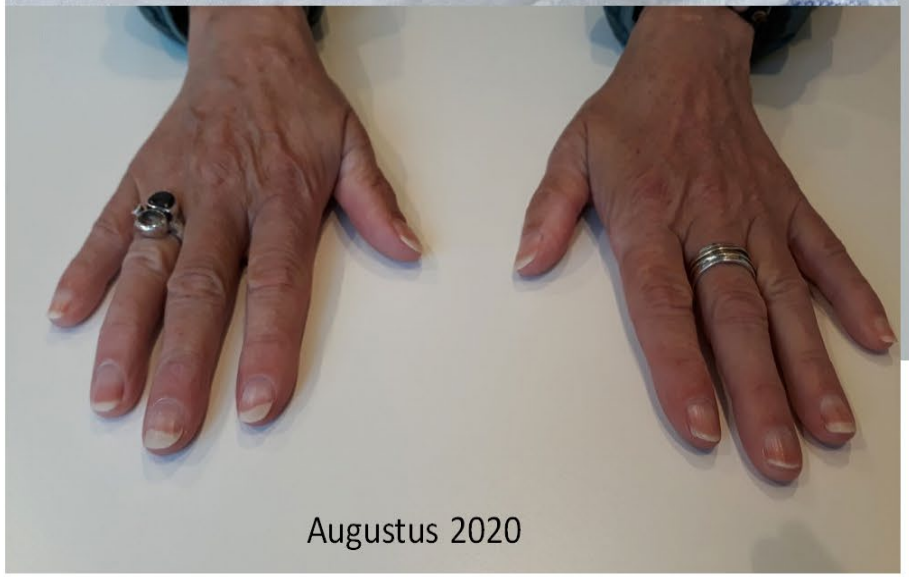
- Bevestiging van diagnose early systemische sclerose
- Vingertopnecrose ikv vasculaire complicatie bij SSc
- Geen evidentie voor pulmonale of cardiale aantasting

Therapie

- Amlor 5 mg 2x/d gestart. In het verleden wel al intolerantie voor Nifedipine en Lercanidipine.
- IV prostaglandines: Prostin infuus in totaal 10 dagen
- Nadien gestart met Sildenafil 2x 20mg + amlor 5mg 2/dag continueren







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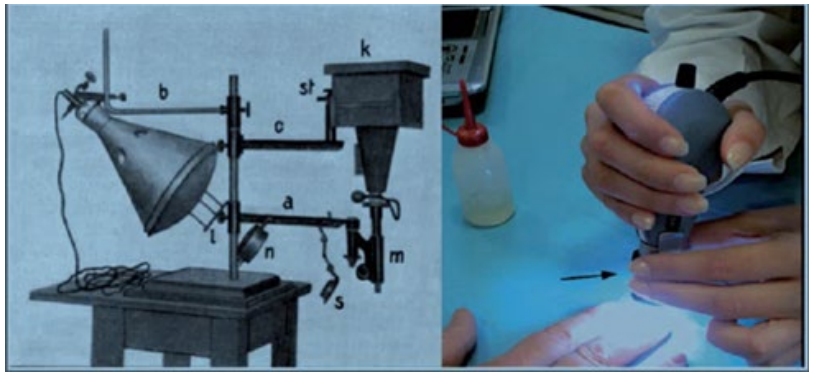

DE ROL VAN CAPILLAROSCOPIE …

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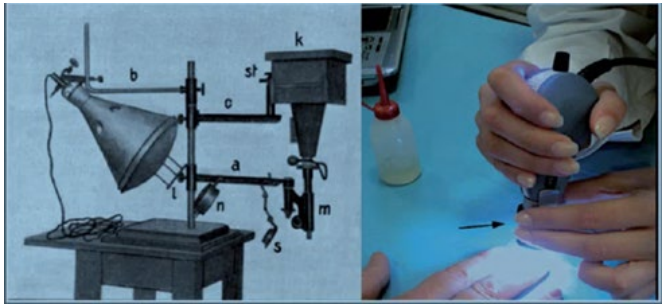
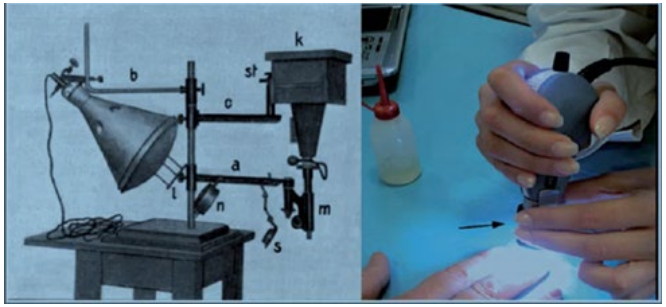
… in het kort



1. Onmisbaar in differentiaal diagnose tussen
   - Primair Raynaud fenomeen (PRP) = niet gerelateerd aan een ziektebeeld
   - Secundair Raynaud fenomeen (SRP) = gerelateerd aan bindweefselaandoeningen

2. Voorspelling van klinische complicaties in CTDs

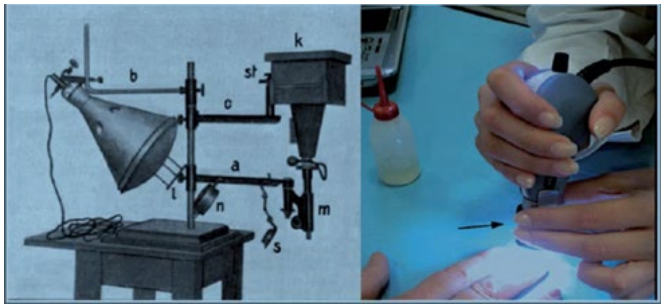
… als uitsluiter



- Diagnose van PRP vereist
  - Normaal capillaroscopie onderzoek
  - ANF negatief
  - Normale sedimentatie
  - Afwezigheid tekens van perifeer vasculair lijden

LeRoy EC, Medsger TA Jr. Criteria for the classification of early systemic sclerosis. J Rheumatol 2001;28:15736.

…als aantoner



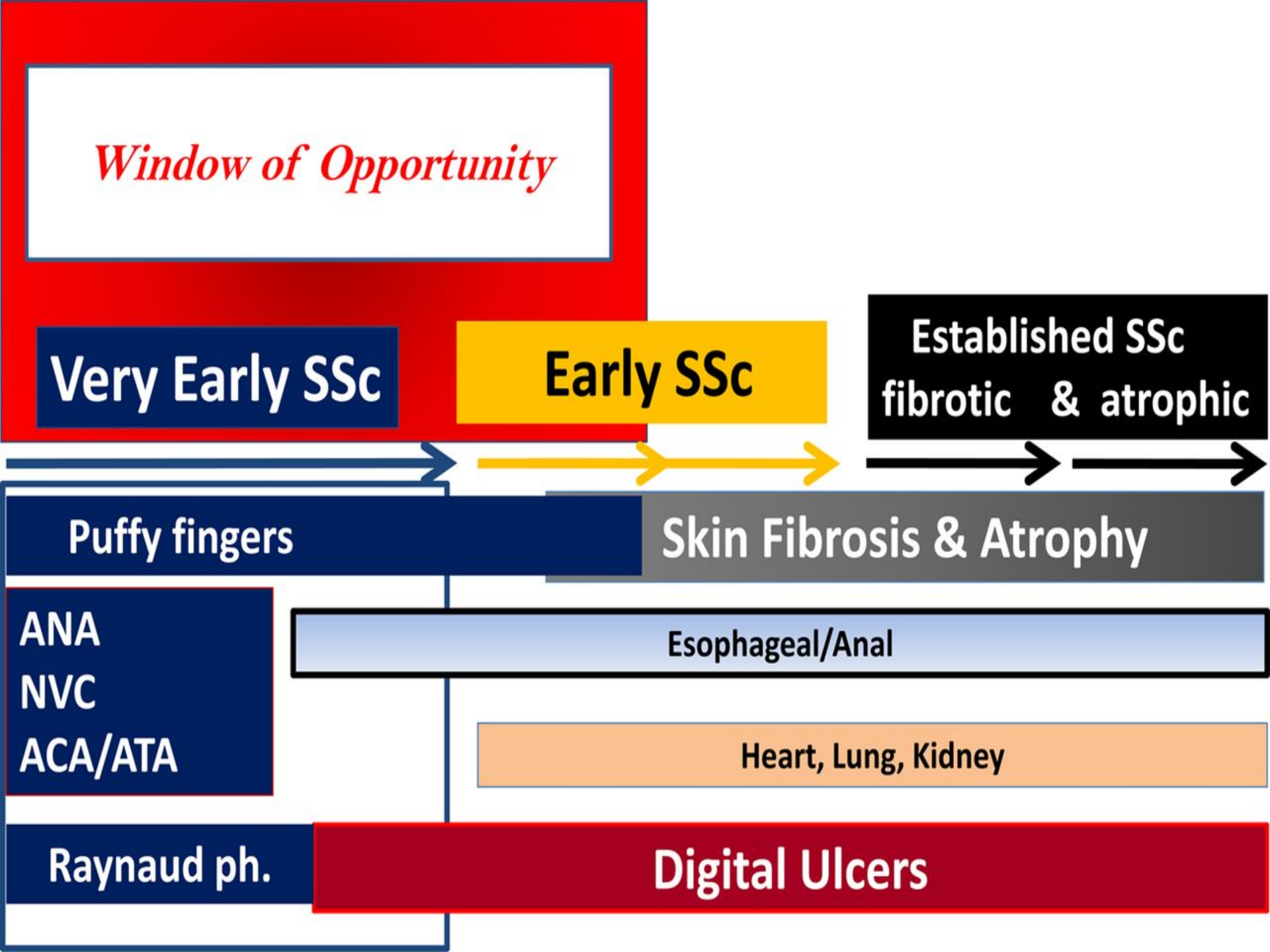
- Scleroderma patroon op capillaroscopie + SSc-specifieke antilichamen

  = diagnose van vroege (preklinische) SSc (Leroy criteria)

- VEDOSS richtlijnen (Very Early Diagnosis Of SSc)

➢ Creëren van *"window of opportunity"* waar de ziekte afgeremd of gestopt kan worden vooraleer er orgaan manifestaties zijn

14State of the art on nailfold capillaroscopy: a reliable diagnostic tool and putative biomarker in rheumatology? Maurizio Cutolo, Vanessa Smith, *Rheumatology*, Volume 52, Issue 11, November 2013, Pages 1933–1940


Window of Opportunity
Very Early SSc
Early SSc
Established SSc
fibrotic & atrophic
Puffy fingers
Skin Fibrosis & Atrophy
ANA
NVC
ACA/ATA
Esophageal/Anal
Heart, Lung, Kidney
Raynaud ph.
Digital Ulcers

VEDOSS: Criteria to trigger early referral

VEDOSS red flags

- **Raynaud's phenomenon**
- **Puffy fingers**
- **Positive antinuclear antibodies**

Avouac J, *et al. Ann Rheum Dis* 2010

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VEDOSS- Very Early Diagnosis Of SSc

Presence of red flags raises suspicion of very early SSc

1st level: Suspicion

1. Capillaroscopy
2. Serology (TOPO-I, ACA)

If either one is positive, diagnosis of very early SSc & further investigations

2nd level: Diagnosis of very early SSc

1. Oesophageal manometry
2. Chest HRCT & PFTs
3. echocardiography

If either one is positive, diagnosis of early SSc & further investigations

3nd level: Diagnosis of early SSc

Avouac J, *et al. Ann Rheum Dis* 2010;

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Casus: Osteoporose

Hoffman Ilse

Dame, ° 1959

- 2001 hysterectomie en ovariëctomie (cysten), kort hormonale substitutie
- Stressfractuur re voet, 2014
- Rookstop sept 2017
- 2017: osteoporose, start prolia + steovit D3 forte
- Moeder heupfractuur op leeftijd van 87 j

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Consultatie jan 2020

- Jan 2019 prolia overgeslagen owv tandextractie, 3 tanden; pas herstart 3 maanden later, dus interval 9 maanden
- April 19 vaststellen fracturen Th9 en Th11, vertebroplastie
- Dexa april 19: T-scores: LWZ -4,6; li heup -2,1; re heup -2,5
- Frax: 10 jaars risico op majeure osteoporotische # 21,9%, heup# 4,5%
- Labo: geen onderliggende problemen

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Vragen

- Inschatten fractuur risico
- Rebound fractuur na onderbreken prolia
- Hoe lang prolia te geven? (‘Drug holidays’zijn standaard bij gebruik van bisfosfonaten)
- Wat met risico op kaaknecrose (ONJ) bij tandHK ingrepen

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FRAX

- Leeftijd
- Geslacht
- Lengte / gewicht
- Eerdere fractuur
- Ouder met heup#
- Roken /alcohol
- Cortico
- Reumatoide artritis
- Secundaire osteoporose
- BMD (T-score heup)

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Prolia (denosumab)

- Rank Ligand inhibitor
- Rank Ligand stimuleert de osteoclasten
- Daling van oestrogeen stimuleert Rank Ligand en veroorzaakt dus osteoclastactivatie
- Prolia bindt aan Rank Ligand en remt de vorming, werking en overleving van de osteoclasten

Prolia in België

- Terugbetaald bij postmenopauzale osteoporose
- Recent ook bij mannen met osteoporose
- MITS contraïndicatie voor PO bisfosfonaat
- Concreet dus vaak bij ingekrompen nierfunctie

Rebound fractuur

- Rebound fractuur ~ rebound bone turnover
- Multipele Case reports
- Fractuur 3-12 maand na stoppen denosumab
- Vaak multipele vertebrale fracturen
- Vaak fractuur op ander niveau dan vertebroplastie

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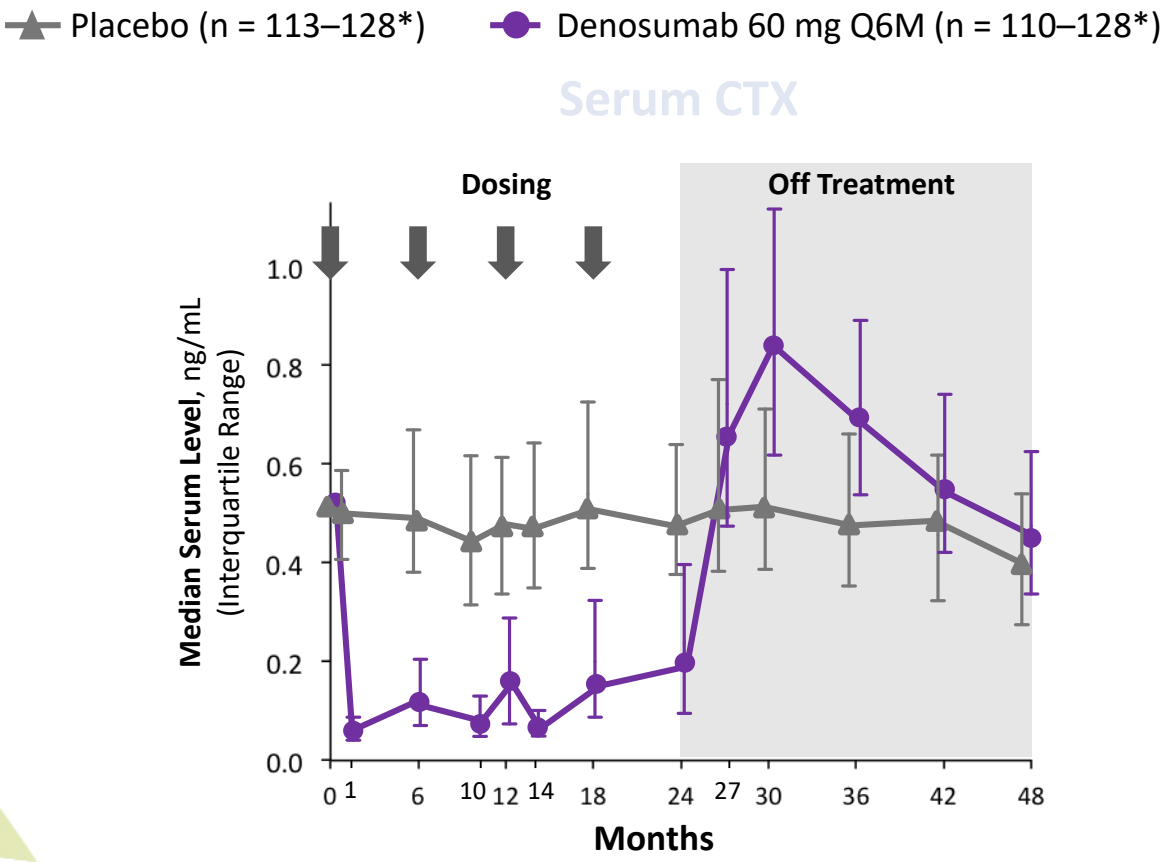
After Denosumab Discontinuation, Bone Turnover Markers Transiently Increase Above Baseline, Peaking at 12 Months From the Last Dose and Then Decreasing Toward Baseline Levels



*Includes subjects enrolled in the off-treatment phase with observed values at Month 0 and time point of interest.

CTX=C-telopeptide of type 1 collagen; PINP=serum procollagen type 1 amino-terminal propeptide; Q6M=every 6 months

Adapted from: Bone HG, et al. *J Clin Endocrinol Metab*. 2011;96:972-980.

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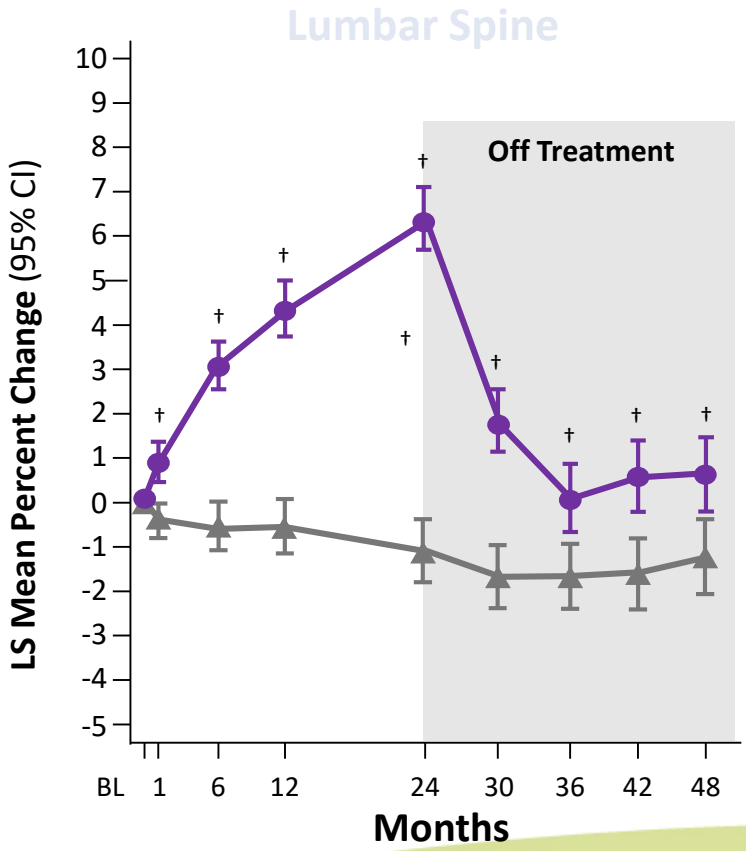
Gasthuisberg Zorgcentrum

After Denosumab Discontinuation, BMD Returns Toward Baseline Levels Within 1–2 Years But Remains Higher Than for Subjects Who Received Placebo

Placebo (n = 110–128*) Denosumab 60 mg Q6M (n = 109–128*)

- †



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When Denosumab Is Discontinued, Overall Fracture Rates Resume to Levels Similar to Those in Subjects Who Have Never Been Treated, Although Multiple Vertebral Fracture Risk Is Higher

	Fracture Rates Per 100 Subject-Years[1]	
	Discontinuing Placebo	Discontinuing Denosumab
	FREEDOM N = 470	FREEDOM N = 327
Any fragility fracture	13.5	9.7
Nonvertebral fracture	4.2	4.1

	Fracture Rates Per 100 Subject-Years (95% CI)[2]	
	Discontinuing Placebo	Discontinuing Denosumab
	FREEDOM N = 470	FREEDOM + Extension N = 1,001
Vertebral fracture*	8.5 (5.5–11.5)	7.1 (5.2–9.0)
Multiple vertebral fractures	3.2 (1.4–5.1)	4.2 (2.8–5.7)

*New or worsening.
CI=confidence interval

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1. Adapted from: Brown JP, et al. *J Bone Miner Res.* 2013;28:746-752. **2**. Cummings SR, et al. *J Bone Miner Res.* 2018;33:190-198.

Risicofactoren voor multipele vertebrale # na stoppen Prolia

- Voorafgaandelijke vertebrale fractuur
- Langduriger stoppen van behandeling
- Minder bij voorafgaandelijke behandeling met bisfosfonaten
- Grotere winst T-score heup tijdens therapie
- Groter verlies T-score heup na stoppen therapie
- Risico op bijkomende fractuur bij vertebroplastie

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Kaaknecrose
Osteonecrosis of the jaw (ONJ)

- Is beschreven bij patiënten op bisfosfonaten en denosumab, zeldzaam ook andere behandelingen
- Definitie: Blootliggend bot in de maxillofaciale regio, >8 weken, zonder radiotherapie vooraf
- Risico bij oncologische dosering veel hoger
- Denosumab dosis voor osteoporose = 60 mg per 6 maand
- Denosumab dosis in onco setting = 120 mg per 4 weken

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Kaaknecrose

- Vaak geassocieerd aan invasieve orale procedures, echter globaal risico van deze procedures blijft laag.
- Op 1621 patiënten onder denosumab die tandprocedure ondergingen, ontwikkelen er 11 kaaknecrose
- Scaling/rootplaning > extractie > implantaat > spontaan tandverlies > kaakchirurgie

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Richtlijnen

- ADA (American Dental Association)

en ONJ taskforce

→ Risico op ONJ weegt niet op tegen risico op fractuur

- AAOMS (American Association of Oral and Maxillofacial surgeons)

→ onvoldoende studies

Andere risicofactoren voor ONJ

- Infectie, osteomyelitis
- Tandvleesproblemen
- Trauma, slecht passend gebit
- Andere aandoeningen: diabetes, anemie, cortico gebruik, roken, alcohol, kanker, kankertherapie, stollingsstoornissen

Besluit

- Geen ‘treat to target’en 'drug holiday' bij Prolia (wel bij bisfosfonaten)
- Bij stoppen Prolia best andere behandeling starten (maar bisfosfonaat in België praktisch niet mogelijk)
- Behandeling 10 jaar (studies)? Levenslang (pragmatisch)?
- Kaaknecrose in osteoporotische setting zeldzaam, andere risicofactoren proberen controleren

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Antireumatische behandelingen & Zwangerschap

De Bock Wouter

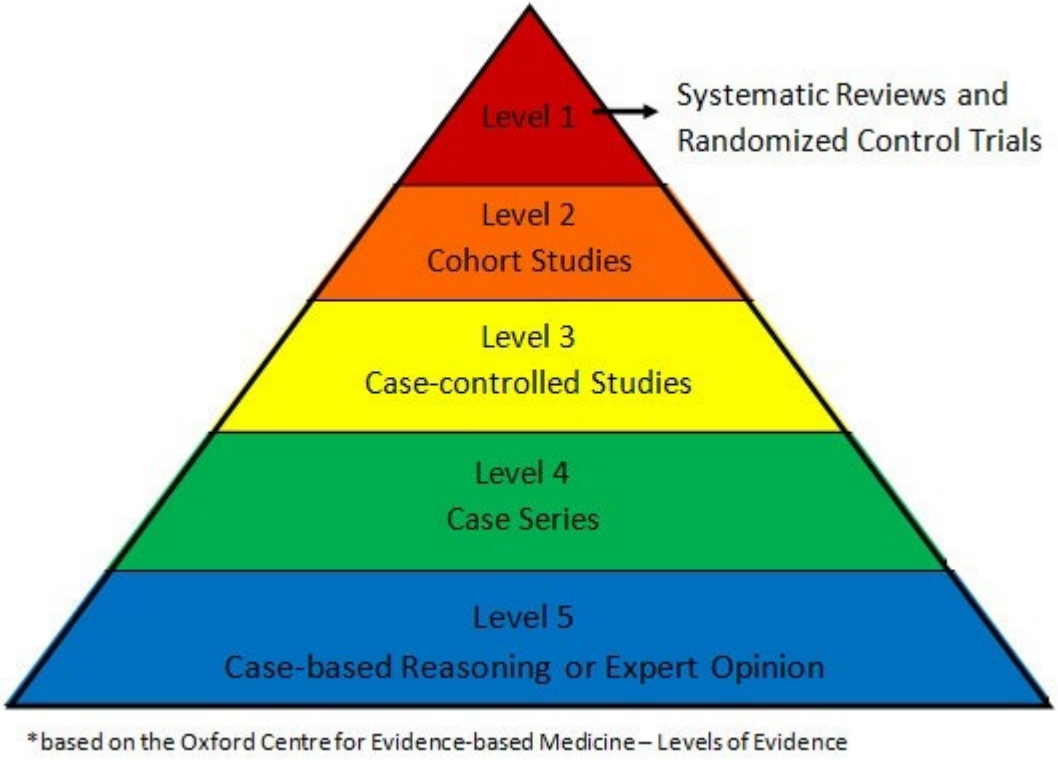
Inleiding

- Verscheidene autoimmuniteitsziekten
- (pre)conceptie, zwangerschap, lactatie
- Vrouw / man / kind
- Evidentie en guidelines vlot beschikbaar (Google)
- Risico aandoening zelf
- Practopics = praktisch

Guidelines

- Beetje opzoekwerk

EULAR



Drug	Type of publication in numbers	References on cohorts and case controls	Total pregnancies† (prospective/ retrospective)	Number of miscarriages of eligible pregnancies‡ (%)	Number of congenital malformations of live births§ (%)	Comments on miscarriages (MC) and/or congenital malformations (CM) compared with control groups and/or background data§	Strength of evidence according to GRADE	Oxford
Non-selective COX inhibitors (classical NSAIDs)	**3 cohorts** 3 case controls	[11–16]	17 992 (7684/10 308)	530/5609 (9.4)	457/ 12 354 (3.7)	No difference MC or CM	++++	2a
Selective COX II inhibitors (rofecoxib, celecoxib, etoricoxib)	3 case controls	[14 15 17]	215 (0/215)	11/71 (15.5)	9/114 (7.9)	Significance for slightly increased rate MC and CM questionable due to confounders	++	3b
Glucocorticoids (any route/ formulation)	**2 cohorts** 5 case controls *17 case reports/series (1 abstract)*	[16 18–23]	3500¶ (94/3406)	70/331 (21.1)	34/3180 (1.1)	MC slightly increased confounded by disease indication, no difference CM compared with control groups	+++	2b
Antimalarials	**2 cohorts** 4 case controls	[16 24–28]	492 (170/322)	20/170 (11.8)	23/492 (4.7)	No difference MC or CM	++++	2a
Sulfasalazine	**2 cohorts** 2 case controls	[16 29–31]	525 (227/298)	12/186 (6.5)	16/339 (4.7)	No difference MC or CM	+++	2a
Leflunomide	**2 cohorts (1 abstract)** 1 case control *4 case reports/series*	[16 32 33]	129 (80/49)	12/122 (9.8)	5/129 (3.9)	No difference MC or CM	+++	2b
Azathioprine	**4 cohorts (1 abstract)** 7 case controls *7 case reports/series (1 abstract)*	[16 31 34–42]	1327 (434/893)	40/559 (7.2)	65/1327 (4.9)	No significant difference MC or CM compared with disease-matched controls	++++	2a
Methotrexate	**2 cohorts** 2 case controls *8 case reports/series*	[16 27 43 44]	372 (332/40)	140/329 (42.6)	15/143 (10.5)	Increased rate MC Increased rate CM with specific pattern	++++	2b
Cyclophosphamide	**2 cohorts** *28 case reports/series (2 abstracts)*	[45 46]	276 (160/116)	No separate studies on MC published	23/86 (26.7)	High rate CM No studies with control group available	+++	2b
Ciclosporin	**2 cohorts** 1 case control *11 case reports/series (1 abstract)*	[47–49]	1126 (1010/116)	137/953 (14.4)	9/261 (3.4)	No difference MC or CM	++++	2a
Tacrolimus	**1 cohort** 1 case control *10 case reports/series*	[47 49]	505 (482/23)	91/344 (26.5)	3/107 (2.8)	MC increase confounded by disease indicationNo difference CM	+++	2b
Mycophenolate mofetil	**2 cohorts** 1 register data *20 case reports/series (2 abstracts)*	[47 50]	333 (199/134)	119/318 (37.4)	48/174** (27.6)	In studies without control group high rate MC and CM with specific pattern	+++	2b
Colchicine	**1 cohort** 1 case control *1 case series*	[51 52]	460 (238/222)	30/417 (7.2)	11/460 (2.4)	No difference MC or CM	+++	2b
IVIG	**3 cohorts** *3 case reports/series*	[53–55]	96 (93/3)	24/93 (25.8)	0/96	No increase of MC or CM compared with disease-matched controls	++	3b
Tofacitinib	*1 case series (abstract)*	–	27 (27/0)	7/27 (25.9)	1/15	In case series and with concomitant MTX exposure high rate MC, no indication of an increased rate CM	+	4
Infliximab	**9 cohorts (1 abstract)** 4 case controls (1 abstract) 2 register data (1 abstract) *16case reports/series (3 abstracts)*	[27 36 56–66]	1161 (968/ 193)	64/676 (9.5)	20/756†† (2.6)	No difference MC or CM	++++	2b
Adalimumab	**10 cohorts (2 abstracts)** 5 case controls (1 abstract) 2 register data (1 abstract) *6 case reports/series (1 abstract)*	[16 27 36 56–58 60–68]	524 (266/258)	23/191 (12.0)	24/350†† (6.9)	No significant difference MC Increased rate CM in one study, no increase compared with disease-matched controls	+++	2b
Etanercept	**3 cohorts** 3 case controls (1 abstract) 2 register data (1 abstract) *11case reports/series (3 abstracts)*	[16 27 57 58 64 65]	332 (213/119)	12/74 (16.2)	9/251†† (3.6)	No difference MC or CM	+++	2b
Certolizumab	**2 cohorts** 1 case control *2 case reports/series*	[61 63 65]	362 (243/119)	52/339 (15.3)	12/267†† (4.5)	No increased rate MC or CM No studies with control group available	++	3b
Golimumab	**1 cohort** *1 case series (abstract)*	[65]	50 (38/12)	13/47 (27.7)	0/26††	With concomitant MTX exposure high rate MC, no indication of an increased rate CMNo studies with control group available	+	4
All TNF inhibitors, including studies not differentiating between them	**10 cohorts (3 abstracts)** 5 case controls (1 abstract) 2 register data (1 abstract) *32 case reports/series (7 abstracts)*	[16 27 36 56–68]	2492 (1734/758)	265/2258 (11.7)	75/2110 (3.6)	No difference in MC or CM in pregnancies exposed to TNF inhibitors compared with controls	+++	2b
Rituximab	1 register data *20 case reports/series*	–	256 (72/184)	48/210 (22.9)	6/172 (3.5)	Increased rate MC confounded by disease indication, no increased rate CMNo studies with control group available	++	4
Anakinra	1 register data *3 case reports*	–	40 (not reported)	4/40 (10.0)	2/34 (5.9)	No increased rate MC or CM No studies with control group available	+	4
Abatacept	*1 case series‡‡* *1 case report*	–	152 (94/58)	40/151 (26.5)	7/87 (8.0)	With concomitant MTX exposure high rate MC and CMNo studies with control group available	++	4
Tocilizumab	1 register data *2 case series (2 abstracts)*	–	218 (180/38)	47/218 (21.6)	5/128 (3.9)	With concomitant MTX exposure high rate MC, no indication of an increased rate CM	++	4
Ustekinumab	1 register data *4 case reports/series (1 abstract)*	–	108 (104/4)	15/108 (13.9)	1/58 (1.7)	No increased rate MC or CM No studies with control group available	++	4
Belimumab	1 register data *1 case series (abstract)*	–	153 (152/1)	41/153 (26.8)	7/ 71 (9.9)	High rate MC and CM Concomitant medication possible confounderNo studies with disease-matched controls available	++	4

Conclusie? – keep it simple: ZS en BV

- NSAID: V
  X COX-2 selectieve
- Colchicine V
- Corticoiden: V
- DMARD: V Hydroxychloroquine en sulfasalazine
  X Methotrexate en leflunomide
  V Azathioprine, tacrolimus, ciclosporine
- Biologicals V Anti-TNF
  X Abatacept, tocilizumab, rituximab
- Kinase inhib X

Praktisch (!)

- Doel: ziekte afremmen bij moeder, foetus / kind niet benadelen
  → afwegen risico
- Bespreking gezinsplanning bij indicatie, bij opstarten R/
  → verrassingen mijden
- Boodschap tot bij gynaecoloog
  → verslag
- (pre)conceptie, zwangerschap, lactatie
- Vrouw / man / kind
- Risico aandoening zelf

Praktisch: NSAID

- COX-2 mijden
- Niet in derde trimester
- FDA 2020: 20-30 weken caveat
- Eerste trimester miskraam (?)
- Borstvoeding: ibuprofene

Praktisch: corticosteroiden

- Lowest effective dose
  - PROM en IUGR
  - HT, DM
  - Infectie, osteoporose
- 5 mg
- (Methyl)prednisolone voorkeur
- Borstvoeding: niet eerste 4u na inname vanaf 20 mg dd

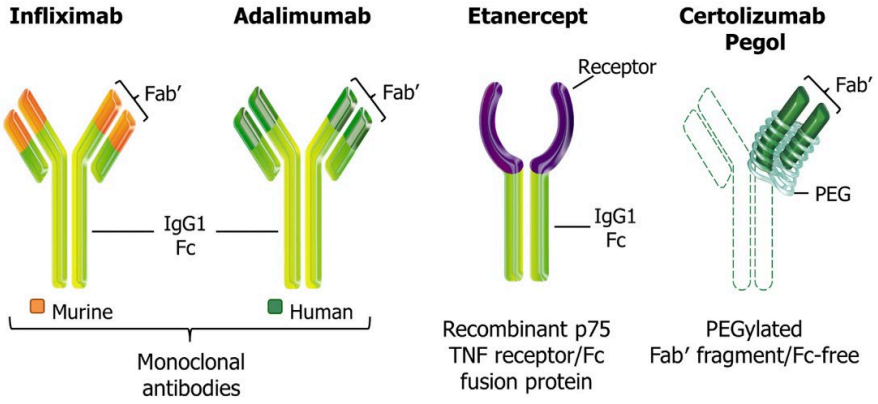
Praktisch: DMARDs

- Hydroxochloroquine
  - SLE: enkel voordeel!
  - Borstvoeding geen probleem
- Sulfasalazine
  - + foliumzuur 0,4 mg dd
  - Borstvoeding: evt stop bij diarree baby

- Methotrexate en leflunomide: Neen

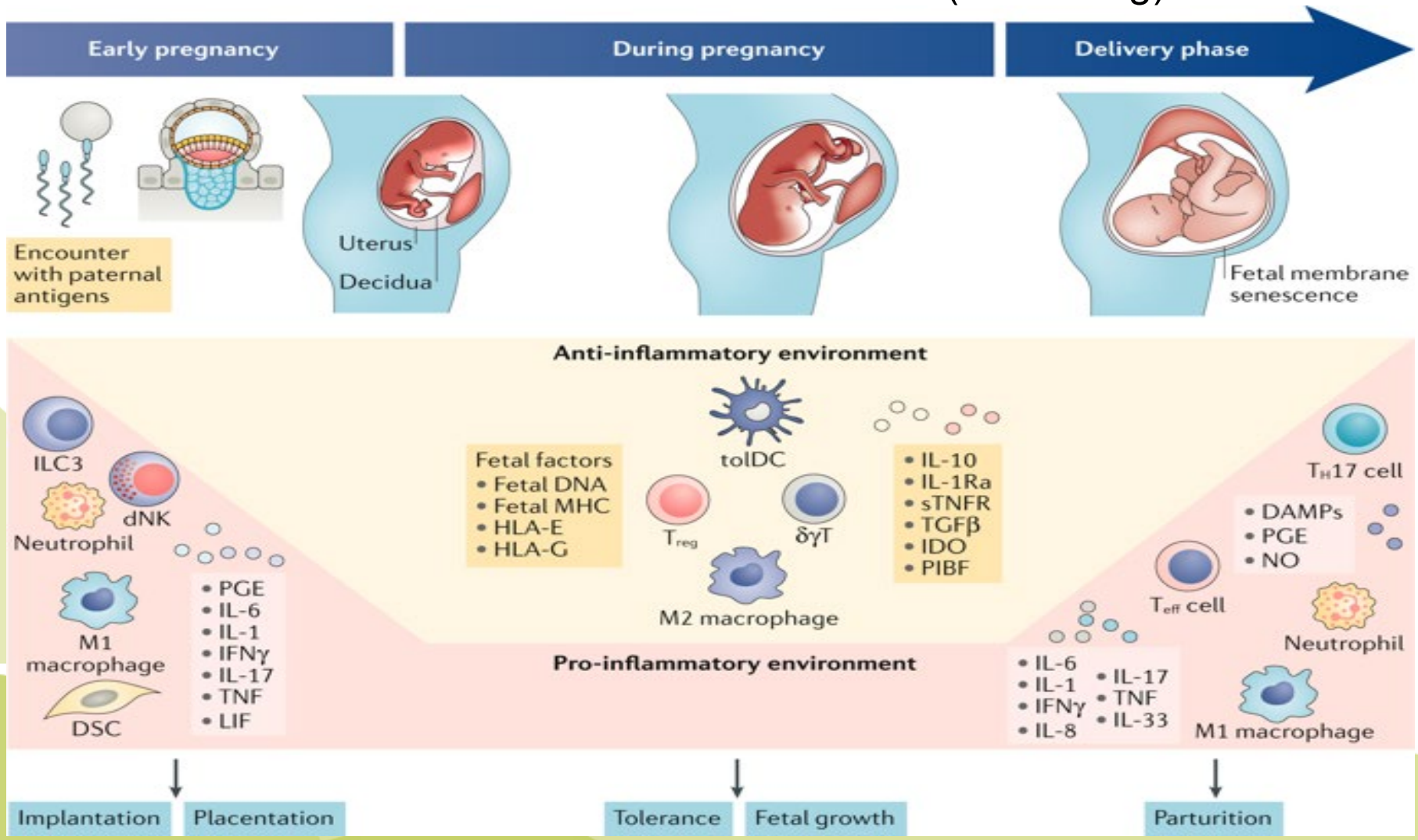
Praktisch: Anti-TNF

- Anti–TNF exceptioneel geëvalueerd
- Multicentrische analyses, registers,…
- VACTERL?
- Breed toepassingsgebied, ook > inflammatoire artropathie
- Richtlijnen vaccinatie kind (preparaat, < 20 w, > 30w, polio / rota)
- Borstvoeding: geen problemen



Aandoening zelf

- Bindweefselaandoeningen
- Spondylartropathie
- Reumatoide artritis (afbeelding)

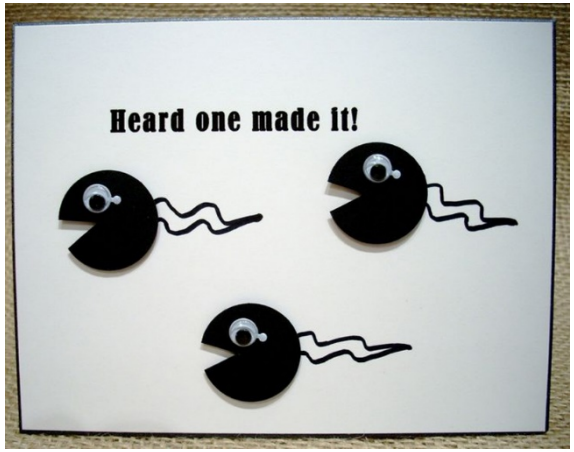


Praktisch:

- Arsenaal: NSAID, Predni, SASP, HCQ, Anti TNF

- 19 jarige studente
- 25 jarige dame
- 30 jarige moeder met 2 kinderen
- 35 jarige dame

- Man… Any age



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Reumatologie

De Bock Wouter
De Clercq Luc
De Knop Kathleen
Hoffman Ilse
Vos Ine

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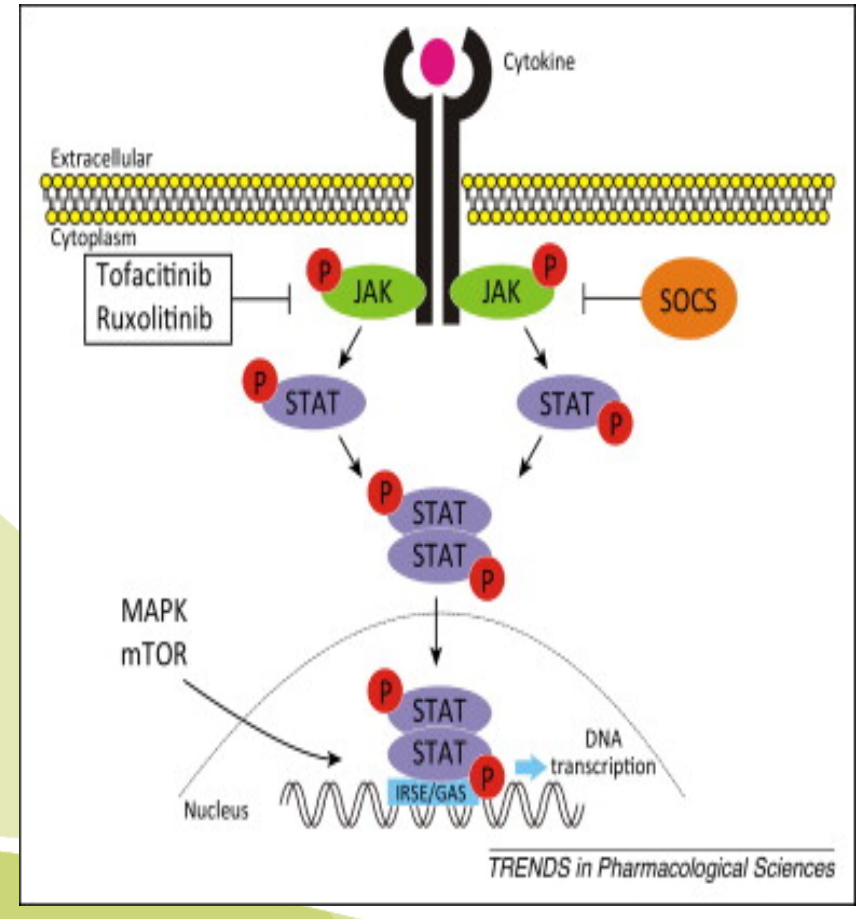
New: “Small molecule drugs”: Janus Kinase (JAK) inhibitors

Kathleen De Knop

“Small molecule drugs”: Janus Kinase (JAK) inhibitors



JAK
- Enzyme for intracellular signaling
- in response to several cytokines

JAK inhibition:
⇒ decreased T-cell activation
⇒ decreased pro-inflammatory cytokine production
⇒ **decreased synovial inflammation and structural joint damage**

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Koenders MI, van den Berg WB. Trends Pharmacol Sci. 2015 Apr;36(4):189-95. doi:10.1016/j.tips.2015.02.001. Epub 2015 Feb 27.

Targeted synthetic DMARDSs tsDMARDS

- Targeted synthetic DMARD:
  - Targeting of a single molecule
  - synthetic chemical agent
- Intracellularly active
- Interfere with signal transduction pathways of variety of cytokines
- Oral intake

JAK inhibitors in rheumatology

Name	Mechanism	Dose
Tofacitinib (Xeljanz®)	JAK1 & JAK3 inhibition (JAK2)	2x 5mg/d p.o.
Baricitinib (Olumiant®)	JAK1 & JAK2 inhibition	4 mg/d p.o.
Upadacitinib (Rinvoq®)	JAK1 & JAK2 inhibition	15 mg/d p.o.
Filgotinib (Jyseleca®)	JAK1 inhibition	100 mg of 200 mg/d p.o.

Selectivity dose dependent

JAK inhibitors in rheumatology

- Same level as bDMARDs
- Reimbursement criteria for RA via TARDIS

  insufficient response/intolerance to 2 csDMARDs

incl. MTX;

  DAS-28 >3,7

  no TBC

- Monotherapy / combination with MTX or other DMARDs

- Rapid response
  - within 2 weeks; further improvement over 3 months

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JAK inhibitors: pretreatment

- Screen for TBC (Mantoux / IGRA and X-ray)
- HBV / HCV/ HIV

- Lipids / Liver tests / renal clearance / PBC

- Check vaccination status
- Pregnancy / lactation

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JAK inhibitors: common side effects

- Infections:
  - HZV
  - URTI
- Anemia / leukopenia
- Elevation liver tests
- Increase lipids
- DVT / PE
- NMSC (no other malignancies)

JAK inhibitors: monitoring

- Liver tests, PBC renal function: every 3m
- Lipids: 3m after initiation

- Hold treatment in case of serious infection
- Annual skin check

- Vaccination: NO LIVE VACCINES

  Influenza yearly

  Pneumococcal infection

  (HZV: inactivated vaccine)

  Corona / COVID-19?

CAVE: acute phase reactant levels may be reduced by JAKi independent of clinical improvement

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Dank u voor uw aandacht

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