Effectiveness and patient satisfaction of a Dutch patient Decision Aid Psoriasis

Gepubliceerd: 25-10-2019 Laatst bijgewerkt: 18-08-2022

Our hypothesis is that the PDA Psoriasis improves the level of SDM (Shared Decision Making) the treatment decision for systemic therapy in patients with psoriasis vulgaris.

Ethische beoordeling	Niet van toepassing
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON28770

Bron
Nationaal Trial Register

Verkorte titel
ESDDAP

Aandoening

Psoriasis Vulgaris

Ondersteuning

Primaire sponsor: Amsterdam UMC - location AMC
Overige ondersteuning: Amsterdam UMC

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Level of SDM measured with OPTION-5 score

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Patient decision aids (PDAs) are known to improve shared decision making (SDM) in various medical fields. They are scare in dermatology and the effect is never studied.
Objective: To assess the effect of a Dutch PDA Psoriasis ('Keuzehulp Psoriasis - Systemische Medicatie') on the level of SDM (objectively assessed by researchers, and subjectively assessed by patients and dermatologists), patients' satisfaction with the physician's consultation and patients decisional conflict'.
Study design: A before-and-after study in two dermatology departments.
Study population: Adult patients with chronic plaque type psoriasis eligible for systemic therapy according to the Dutch national guideline psoriasis.
Intervention (if applicable): A Dutch PDA psoriasis and corresponding implementation training for dermatologists.
Main study parameters/endpoints: Primary study parameter; level of SDM measured with OPTION-5 score and secondary study parameters; level of SDM measured with SDM-Q-9 score, SDM-Q-Doc score and CollaboRATE score; Patient Satisfaction with the consultation measured with VAS score 0-9, and decisional conflict measured with Decisional Conflict Scale.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: The consultations will be audio taped. The patients who will be asked to use the PDA psoriasis this might take 30 minutes to complete, which can be done at home. The questionnaire for patients takes about 10 minutes to complete, for physicians this is approximately 2 minutes.

Doel van het onderzoek

Our hypothesis is that the PDA Psoriasis improves the level of SDM (Shared Decision Making) the treatment decision for systemic therapy in patients with psoriasis vulgaris.

Onderzoeksopzet

Sep 2019 - Jan 2020; before study
Jan 2020 - Feb 2020; after study

Onderzoeksproduct en/of interventie

A Dutch PDA psoriasis ('Keuzehulp Psoriasis - Systemische Medicatie') and corresponding implementation training for dermatologists.

Contactpersonen

Publiek

Amsterdam UMC
Astrid van Huizen

020-5668109

Wetenschappelijk

Amsterdam UMC
Astrid van Huizen

020-5668109

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

-Age of ≥ 18
-Confirmed psoriasis by (resident) dermatologist
-Eligible for systemic therapy according to the Dutch national guideline psoriasis

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

-Insufficient understanding of the Dutch language or cognitively unable to complete Dutch questionnaires.
-Absence of willingness to use the PDA Psoriasis

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd

Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	10-09-2019
Aantal proefpersonen:	30
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

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	NL8116
Ander register	Not applicable, this is a non-WMO (Medical Research Involving Human Subjects Act) study confirmed by METC AMC : W19_299 #19.356 app (reference number non-WMO study)

Resultaten