A prospective explorative controlled study on cannabinoids to treat chronic pain in epidermolysis bullosa.

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Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28210

Bron
NTR

Verkorte titel
C4EB

Aandoening

Epidermolysis Bullosa

Ondersteuning

Primaire sponsor: University Medical Center of Groningen
Overige ondersteuning: DEBRA-UK

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

• To determine the effect of Transvamix, relative to placebo, on participant reported pain scores of the quality “unpleasantness” in EB patients with chronic pain.

Toelichting onderzoek

Achtergrond van het onderzoek

There is an unmet need for more effective pain alleviation in EB patients. EB patient anecdotes on the use of cannabinoid-based medicines (CBMs) are in line with current science aimed at assessing the effectiveness of CBMs for chronic pain conditions. Until now evidence on the effectiveness of CBMs is moderate and is inconclusive. As the pain quality item “unpleasantness” delineates EB pain, we hypothesize the modulation of affective pain processing in the brain by way of intervention with Transvamix (comprising THC and CBD) - objectified by functional magnetic resonance imaging (fMRI).

Doel van het onderzoek

As the pain quality item “unpleasantness” delineates EB pain, we hypothesize the modulation of affective pain processing in the brain by way of intervention with Transvamix (a CBM comprising THC and CBD) - objectified by functional magnetic resonance imaging (fMRI).

Onderzoeksopzet

0, 2 & 8 weeks

Onderzoeksproduct en/of interventie

Transvamix oil (THC 10%, CBD 5%)

Contactpersonen

Publiek

Universitair Medisch Centrum Groningen
Nicholas Schrader

(050) 36 12945

Wetenschappelijk

Universitair Medisch Centrum Groningen

Nicholas Schrader

(050) 36 12945

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Clinical diagnosis, supplemented by genetic analysis, immunofluorescent diagnostics or electron microscopy of congenital epidermolysis bullosa (EB). Including the subtypes recessive dystrophic EB, dominant dystrophic EB, junctional EB and EB simplex.
- At least 16 years of age from the date of onset of participation.
- Can read and write in the Dutch language.
- Mentally competent and legally able to appreciate informed consent.
- Reporting an average pain or pruritus mean score ≥4 on NRS (0-10) averaged throughout the previous week at one of the following times of day: morning, afternoon or evening.
- Negative COVID-19 testing will be required prior to participation

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Patients enrolled in other clinical trials that do not allow for a deviation in treatment.
- Have experienced myocardial infarction or clinically significant cardiac dysfunction within the last 12 months or have had a cardiac disorder that, in the opinion of the investigator would have put the participant at risk of a clinically significant arrhythmia or myocardial infarction.
- Patients with known psychotic disorder (including the use of antipsychotic medications), or a history of suicidal ideation.
- Female patients of child-bearing potential and male participants whose partner was of child-bearing potential, unless willing to ensure that they or their partner used effective contraception.
- Patients who have had significantly impaired renal or hepatic function in the last 12 months.
- The patient is currently using or has used cannabis or cannabinoid-based medications within 30 days of study entry and was unwilling to abstain for the duration of the study.
- Patients unwilling or unable to refrain from driving road vehicles and/or using potentially dangerous machinery where sufficient concentration is necessary.
- Patients unable to stay within the Netherlands for the duration of the study period.
- History of addiction and/or hospital admission due to addiction to recreational or pharmaceutical drugs.
- Patients with contradictions for MRI determined through the MRI safety form

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	02-05-2022
Aantal proefpersonen:	16
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Toelichting
N/A

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	NL9347
Ander register	METC UMCG : METc: 2021076

Resultaten

Samenvatting resultaten
N/A