A Methodology Study Quantifying Mast Cell Density in Healthy Volunteers

Gepubliceerd: 13-10-2020 Laatst bijgewerkt: 15-05-2024

Quantification of mast cell density in human volunteers will inform future interventional studies that impact mast cell proliferation and/or turnover

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

Samenvatting

ID

NL-OMON29591

Bron
Nationaal Trial Register

Verkorte titel
TBA

Aandoening

Mast cell mediated diseases

Ondersteuning

Primaire sponsor: Third Harmonic Bio
Overige ondersteuning: Third Harmonic Bio

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Skin Mast cell density measurements over time within individuals

Toelichting onderzoek

Achtergrond van het onderzoek

The primary objective of this study is to characterize the repeatability (measurement in one subject at different time points and from different samples at the same time points) and reproducibility (measurement between subjects) of mast cell measurements in full thickness skin biopsies via histochemical staining in healthy volunteers.

Doel van het onderzoek

Quantification of mast cell density in human volunteers will inform future interventional studies that impact mast cell proliferation and/or turnover

Onderzoeksopzet

Day 1 and 14

Onderzoeksproduct en/of interventie

None

Contactpersonen

Publiek

Third Harmonic Bio (Sponsor) / QPS, Groningen (CRO)
Steven Sweeney

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Healthy male and female subjects (healthy defined as no clinically relevant abnormalities identified by a detailed medical history, physical examination, including vital sign assessments) aged between 18 and 55 years of age (inclusive) at the time of screening.
2. Understands the study and gives written informed consent for study participation.
3. Body Mass Index (BMI) ≥17.5 kg/m2 and ≤ 30.0 kg/m2.
4. Willing to follow all study restrictions and instructions.
5. Subjects must be willing and able to undergo skin biopsies.
6. Subjects must have the ability to communicate well with the Investigator in the local language and be willing to comply with the study restrictions.
7. Subjects must agree not to post any personal medical data related to the study or information related to the study on any website or social media site (e.g., Facebook, Twitter, TikTok, etc.) until the study has completed.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Subject reports a recent or current medical condition that might significantly affect the outcome of the study as decided by the Principal Investigator.
2. Pre-existing urticaria or atopic dermatitis.
3. History of melanoma.
4. History of allergic disease (severe allergies, food allergies, etc.) that require prescription medication.
5. Recent (within 7 days) allergic reaction (e.g. bee stings, food, or other allergen).
6. History of asthma requiring the use of inhaled or systemic prescription medication within the past 5 years.
7. Subject is symptomatic or being actively treated for an acute disease or progressive chronic disease.
8. Subject sensitivity or allergy to Lidocaine.
9. Subject has a fever defined as a temperature ≥ 37.8 °C or any reports of fever resulting from bacterial or viral infection within 7 days prior to Day 1.
10. Subject is on an active nonsteroidal anti-inflammatory drug or antihistamine therapy defined as at least one dose daily for ≥ 7 days within 14 days prior to Day 1.
11. Subject is on active immunosuppressive drug defined as at least one dose within 28 days prior to Day 1.
12. Frequently used any tobacco-containing (e.g., cigar, cigarette or snuff) or nicotine-containing product (e.g., nicotine chewing gum, nicotine plasters, or other product used for smoking cessation) within 1 month prior to enrollment. Frequent use is defined as 3 or more days per week.
13. History of regular alcohol consumption within 3 months of the study defined as an average weekly intake of >21 alcoholic drinks/week for men or >14 alcoholic drinks/week for women.

14. Subject has donated >450 mL of blood within the previous 90 days prior to Screening.
15. Subject participated in a clinical investigation within the previous 30 days prior to Screening.
16. Subject reports diagnosis of, or suspected, PKU (phenylketonuria) disorder.
17. History of excessive bleeding or any other contraindication for skin biopsy.
18. Subject has forearm tattoos that interfere with the ability to collect a biopsy from a tattoo-free area.
19. Any medical history that may impact the safety of the subject during participation.
20. Positive test results for Hepatitis B, Hepatitis C, or HIV at Screening.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	09-11-2020
Aantal proefpersonen:	12
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	13-10-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 49094
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9025
CCMO	NL75384.056.20
OMON	NL-OMON49094

Resultaten