A Methodology Study Quantifying Mast Cell Density in Healthy Volunteers

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON29591

Source
NTR

Brief title
TBA

Health condition

Mast cell mediated diseases

Sponsors and support

Primary sponsor: Third Harmonic Bio
Source(s) of monetary or material Support: Third Harmonic Bio

Intervention

Outcome measures

Primary outcome

Skin Mast cell density measurements over time within individuals

Secondary outcome

Skin Mast cell density measurements between individuals

Study description

Background summary

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.

Study objective

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

Study design

Day 1 and 14

Intervention

None

Contacts

Public
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Scientific
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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-11-2020
Enrollment:	12
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	13-10-2020
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 49094
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

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

Study results