A methodology study quantifying mast cell density in healthy volunteers

Published: 02-11-2020
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To quantify and assess intra- and inter-subject variability in mast cell density among healthy male and female volunteers. Serum tryptase values will also be quantified.

Ethical review	Approved WMO
Status	Completed
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON49094

Source
ToetsingOnline

Brief title
CS0358-200434

Condition

- Other condition

Synonym
not applicable

Health condition

methodology study

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Biopsy, Mast cell density, Methodology

Outcome measures

Primary outcome

The following are defined as the study parameters:

* Skin mast cell density

* Serum tryptase

* Adverse Events (AEs)

Secondary outcome

Not applicable

Study description

Background summary

Mast cell numbers vary significantly between different anatomical sites when analyzed in biopsies obtained from different subjects. This study is designed to quantify the variability of mast cell numbers within a subject from biopsies obtained in the same anatomical region on the same day and approximately 14 days apart. Comparing samples from the same arm at the same time, from the same arm at different times, and from different arms will help inform the utility of measuring mast cell numbers in future interventional studies with an investigational product that has the potential to deplete mast cells.

Study objective

To quantify and assess intra- and inter-subject variability in mast cell density among healthy male and female volunteers. Serum tryptase values will also be quantified.

Study design

This is a single site, non-interventional, methodology study in healthy subjects.
After assessing eligibility during a 28-day screening period, 12 subjects will

participate in the study. On Day 1 and Day 15 (± 2 days), subjects will come to the study center. On each of these days, a blood sample for serum tryptase will be drawn and subsequently two skin biopsies, each collecting 3 mm of skin, will be performed. Subjects will be released from the unit on the same day, once all procedures have been performed. On Day 22 (± 2 days), a follow-up safety phone call will take place.

Study burden and risks

The risk is small, the subjects will be closely monitored. The subjects will be regularly questioned for any side-effects and regular safety tests are scheduled (ECG/vital signs/physical exam/safety lab testing). The subject will be asked to report, as soon as possible, any changes in physical and/or mental well being.

The site where skin is collected, may be tender and/or painful for 1 or 2 days after the biopsy. If the wound starts to bleed excessively, and/or becomes red and warm, you have to contact the research physician.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

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.

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.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	02-11-2020
Enrollment:	12

Type:	Actual

Ethics review

Approved WMO Date:	02-11-2020
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 29591
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL75384.056.20

Study results

Date completed:	12-12-2020
Results posted:	19-05-2021

First publication
26-03-2021