

# A methodology study quantifying mast cell density in healthy volunteers

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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.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Completed
<b>Health condition type</b>	Other condition
<b>Study type</b>	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 ( $\pm 2$  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 ( $\pm 2$  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)  $\geq 17.5 \text{ kg/m}^2$  and  $\leq 30.0 \text{ kg/m}^2$ .

### 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: NTR

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