# Detection Of Drugs In exhaled Air

Published: 01-06-2023
Last updated: 06-05-2024

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| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Exposures, chemical injuries and poisoning |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON53342

**Source**
ToetsingOnline

**Brief title**
DODIA

### Condition

- Exposures, chemical injuries and poisoning

**Synonym**
Intoxication and poisoning

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Academisch Medisch Centrum
**Source(s) of monetary or material Support:** Ministerie van OC&W

### Intervention

**Keyword:** Breath, Detection, Drugs, Exhaled air

## Outcome measures

### Primary outcome

The primary endpoint is a difference in the intensity of GC-MS variables (M/Z ratio's at a specific retention time) between time points before and after paracetamol intake, determined via non-parametric univariate paired tests (Wilcoxon signed rank).

### Secondary outcome

The secondary endpoint is the association between concentrations of paracetamol in the saliva and the obtained multivariate models and retaining univariate ion fragments via ANCOVA.

# Study description

### Background summary

Paracetamol is used for pain or fever management. Overdose with paracetamol occurs frequently and causes significant liver injury, potentially resulting in fatal liver failure. Fast detection of paracetamol intake can support a tentative clinical diagnosis of paracetamol overdose. Exhaled air is an exciting matrix since it can be collected quickly. Over the last couple of decades, exhaled air has been identified as a possible matrix for detecting xenobiotic substances, including amphetamines, tetrahydrocannabinol, propofol, methadone, and valproic acid. We hypothesize that a similar route of excretion exists for paracetamol.This excretion route would make exhaled air a potential matrix for non-invasive paracetamol sampling instead of the current golden standard of invasive blood sampling. This could lead to feature developments in non-invasive paracetamol screenings at the emergency care department. Here, we want to develop an analytical method to determine the presence of paracetamol and related metabolites in exhaled air via GC-MS.

### Study objective

The primary objective is to develop a proof-of-concept analytical method to detect and identify volatile organic compounds linked to paracetamol in exhaled

air. The secondary objective is to study the association between concentrations of paracetamol in the saliva and quantative outcomes of identified compounds in exhaled air.

### Study design

Openlabel, single centre, cross-over study

### Intervention

Volunteers will receive two 500 mg paracetamol tablets orally in the fasting state. If early data analyses are successful, the volunteers will receive one 500 mg paracetamol tablet in the fasting state, separated by a wash-out period of a minimum of 1 week. During both days, 3 saliva samples and 10 breath samples are taken.

### Study burden and risks

Each subject will have 2 hospital visits separated by a wash-out period of at least 1 week. The subject will orally take 2 tablets of 500 mg paracetamol on the first hospital visit and 1 tablet of 500 mg on the second hospital visit. Dietary restrictions are in place 8 hours before administration and during the 4-hour sampling period. Breath samples will be withdrawn at 10 time points over 4,5 hours. Saliva samples will be withdrawn at 3 time points over 4,5 hours. The risk associated with the treatment are limited since paracetamol does not have common side effects.

## Contacts

**Public**
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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)

## Inclusion criteria

Age between >= 18 and <= 65 years.
The volunteer is able and willing to give written informed consent.
Have a BMI between 18,5 and 30 kg/m2
Able and willing to swallow tablets
Willing to follow the dietary restrictions

## Exclusion criteria

Known substance abuse, psychotic disorders, and/or other diseases expected to interfere with the study or the patient*s safety.
A body weight <= 50 kg.
When unable to exhale the specified volume of air into the collection device at the time of inclusion.
When unable to collect saliva
Smoking tobacco products 1 week before the start of the study intervention
Known pregnancy or breast feeding
Known liver failure (ALAT, ASAT above 3x upper normal limit) or liver disease related coagulation deficiencies (INR > 1.0)
In case of being in a dehydrated state
In case of chronic undereating
Administration of paracetamol within 1 week before start of the study intervention
Known allergy to paracetamol
Alcohol intake 24 hours before paracetamol administration

# Study design

## Design

**Study type:** Interventional

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

## Recruitment

NL

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| Recruitment status: | Recruiting |
| Start date (anticipated): | 14-12-2023 |
| Enrollment: | 12 |
| Type: | Actual |

# Ethics review

Approved WMO

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| Date: | 01-06-2023 |
| Application type: | First submission |
| Review commission: | METC Amsterdam UMC |

# Study registrations

## Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

## In other registers

| Register | ID |
| --- | --- |
| CCMO | NL83513.018.22 |