# Collection/analysis of oral fluid from the tongue of persons that have smoked cannabis

Published: 18-10-2011 Last updated: 28-04-2024

Purpose of this study is to investigate whether a sample of oral fluid and sweat on the hands may be used to detect traces of cannabis and to test how log after smoking cannabis traces can be detected.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

# Summary

## ID

NL-OMON35142

**Source** ToetsingOnline

Brief title BAAB 01-NE

## Condition

• Other condition

#### Synonym

nvt

#### **Health condition**

het is een analytisch-chemische studie met samples van vrijwilligers

#### **Research involving**

Human

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## **Sponsors and support**

**Primary sponsor:** Biosensor Applications **Source(s) of monetary or material Support:** de fabrikant van de Biosens600;Biosensor Applications

## Intervention

Keyword: Biosensor, cannabis, saliva

## **Outcome measures**

#### **Primary outcome**

Criteria for evaluation:

cannabis contents in saliva samples, both samples analysed by the external

laboratory by the conventional methods and those analysed by means of the

Biosens600.

#### Secondary outcome

cannabis contents in sweat samples, obtained by the Biosens600

# **Study description**

#### **Background summary**

The equipment being studied is the BIOSENS®600. The device works according to a unique method that combines immunoassays and 'Surface Acoustic Wave' (SAW) technology. The results of the tests are available within minutes and may be done on-site. the device is meant to be used by the police in traffic control or by customs. Testing by means of the BIOSENS®600 is less burdensome for the person being tested than current methods for which blood and urine samples are being used to test for cannabis use.

#### **Study objective**

Purpose of this study is to investigate whether a sample of oral fluid and sweat on the hands may be used to detect traces of cannabis and to test how log after smoking cannabis traces can be detected.

## Study design

Open, non randomized study with maximally 8 subjects that will be asked to smoke cannabis on one occasioin. There will be 4 volunteers to not smoke (nor smoking any cannabis and not smoking any tobacco).

Oral and saliva samples will be taken from the volunteers before and at 1, 2, 3, 4, 5, and 6 hours after smoking cannabis. Before and 4 and 6 hours after smoking cannabis, a sweat sample will be taken of the fingertips from the volunteers.

## Intervention

Mandatory assessments:

- 24 hours prior to study not smoking any cannabis;
- not eating or drinking until 4 uur after smoking cannabis;
- not eating and drinking till 15 minutes before oral sample taking;
- not drinking any alcohol during the entire study day;
- smoking cannabis at the pre-defined time;
- for the controles only: not smoking any cannabis and tobacco during the study day.

Sampling:

- Before and at 1, 2, 3, 4, 5, and 6 hours after smoking cannabis: oral and saliva sample

- Before and at 4 and 6 hours aftere smoking cannabis: sweat sample

#### Study burden and risks

There are no adverse effects expected with taking saliva and sweat samples. The most important effect of cannabis is the pleasant feeling it is causing (\*high\*). Usually, one feels well, relaxed, experience colours more intense, experience music more intense, the sense of feeling space and time differs, fantasy is increasing. Sometimes, psychotic symptoms of fear and panic may arise, concentration and memory might decrease and the heart beats faster. All these symptoms disappear when the cannabis smoked during this study ceases to work. The subjects asked to participate to this study are familiar with the use and effects of cannabis.

# Contacts

**Public** Biosensor Applications

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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. Male or female, age 18-65 years
- 2. Provision of signed written informed consent
- 3. History of cannabis smoking (defined as smoking cannabis at least 5 times in the last year)
- 4. Have not smoked cannabis the last 24 hours prior to study start
- 5. Willing to provide oral, saliva, and sweat samples

## **Exclusion criteria**

1. Any subject with damaged oral conditions, who in the investigators opinion should not participate

2. Any subjects who in the investigator\*s opinion would be unsuitable for the study

# Study design

# Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

## Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-02-2012
Enrollment:	12
Туре:	Actual

## Medical products/devices used

Generic name:	Biosens600: analysis of surface with traces of cannabis
Registration:	Yes - CE intended use

# **Ethics review**

Approved WMO	
Date:	18-10-2011
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

No registrations found.

## In other registers

Register

ССМО

ID NL37831.056.11