Pharmacokinetics of Drugs of Abuse in Urine and Saliva of Chronic Drug Users

Published: 27-03-2012
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To obtain pharmacokinetic data to apply drugs screening in saliva for the addiction setting.

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

Summary

ID

NL-OMON39094

Source
ToetsingOnline

Brief title
Drug screening in Urine and Saliva (DUS)

Condition

- Other condition

Synonym
Drug addiction, Drug dependence

Health condition

drugsverslaving

Research involving
Human

Sponsors and support

Primary sponsor: Maasstadziekenhuis
Source(s) of monetary or material Support: ziekenhuisapotheek/MaasstadLab budget en Delta budget t.b.v. onderzoek

Intervention

Keyword: Drugs of abuse, Oral Fluid, Pharmacokinetics, Urine

Outcome measures

Primary outcome

To determine the detection time (time until cutoff), mean concentration (Cmax),

the time on Cmax (Tmax), the halflife (t1/2) of drugs in oral fluid after using

the drugs.

Secondary outcome

Not relevant.

Study description

Background summary

Testing of drugs of abuse is used in addiction threatment settings, in toxicological research, in justice settings and in workplace testing. A screening in urine is used in most situations. Testing in oral fluid has advantages compared to urine in simplicity of sample collection. However, the most pharmacokinetic data (e.g. duration of detection in oral fluid) are obtained by studies with healthy volunteers who were administered single doses, while some studies indicate that pharmacokinetics in chronic users is a lot different compared to these standardised research groups. It is necessary to obtain more pharmacokinetic data about drugs in oral fluid of chronic drug users to generate a reliable judgment of an outcome of a drug screening in oral fluid.

Study objective

To obtain pharmacokinetic data to apply drugs screening in saliva for the addiction setting.

Study design

Cohort study.

Study burden and risks

The volunteer has to rinse the mouth with water en hold the oral fluid collection system in the mouth for maximal 10 minutes (average 5 minutes). This is not irritating and has not a strange taste. In the research period of 3 days are 9 oral fluid samples and 3 fingerprick blood samples per day needed. Besides the regular urine screenings in the addiction threatment institution (1-3 times per week), 1-2 extra urine samples are needed during the research period. Urinating with supervision is oncomfortable but familiar to the volunteer. There are no risks for the volunteer while participating in the study.

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

- Age of 18 years or older
- Patient competence
- Recent admission in addiction treatment institution
- Threatment for drug addiction (amphetamine, methamphetamine, cocaine, opiates, cannabinoids) with abstinent policy
- Informed consent

Exclusion criteria

- Not willing to or unable to produce oral fluid.
- (Suspicion of) manipulating the oral fluid or urine sample.
- (Suspicion of) no compliance to the abstinent threatment.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	13-03-2013
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	28-03-2012
Application type:	First submission

Review commission:	TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (Rotterdam)
Approved WMO Date:	11-04-2013
Application type:	Amendment
Review commission:	TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (Rotterdam)
Approved WMO Date:	18-07-2013
Application type:	Amendment
Review commission:	TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (Rotterdam)

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	NL39149.101.11