Pharmacokinetics in Plasma and Saliva of a Single Dose Caffeine in Healthy Volunteers

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- To establish the pharmacokinetic profiles of saliva and plasma concentration of caffeine after a caffeinated beverage (two cups of espresso coffee) containing approximately 135 mg caffeine in total or one capsule containing 200 mg caffeine in...

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

Summary

ID

NL-OMON37682

Source
ToetsingOnline

Brief title
Caffeine PK

Condition

- Other condition

Synonym
N/A

Health condition

N/A

Research involving
Human

Sponsors and support

Primary sponsor: Centre for Human Drug Research
Source(s) of monetary or material Support: Internal study CHDR

Intervention

Keyword: Caffeine, concentration, healthy volunteers, saliva/plasma ratio

Outcome measures

Primary outcome

Descriptive statistics of PK in blood and saliva and PK modelling.

Secondary outcome

N/A

Study description

Background summary

Despite caffeine*s frequent use in by children and adolescents, very little is known about the relationship between the time-course of its effects related to blood levels in this age group. Recently, a study was performed in healthy adolescents in whom acute effects of a caffeinated beverage containing approximately 135 mg caffeine were measured non-invasively using the NeuroCart test battery (CHDR0918, data on file). As blood sampling is undesirable in minors in the setting of a non-therapeutic study, saliva samples were collected to measure caffeine concentration. Statistically significant caffeine effects were found and saliva samples were analyzed successfully using a validated high-performance liquid chromatography method. However, plasma caffeine levels need to be estimated for population PK/PD analysis of the obtained data. By combining saliva caffeine data with pharmacokinetic data in plasma, a PK model could be build built that provides us with estimated plasma drug levels in adolescents needed for population PK/PD analysis. As published data in adults were pooled and therefore not readily available for use, a study in healthy volunteers is needed in which both plasma and saliva samples will be obtained prior and post administration of caffeine. As caffeine saliva PK may be complicated by pH partitioning, the possible effect of saliva pH and/or flow on caffeine saliva concentration will be investigated. In addition, caffeine will be administered via a beverage and a capsule, on separate occasions. Any differences will be observed to investigate the extent of oral

contamination/residue after drinking a caffeinated beverage.

Study objective

- To establish the pharmacokinetic profiles of saliva and plasma concentration of caffeine after a caffeinated beverage (two cups of espresso coffee) containing approximately 135 mg caffeine in total or one capsule containing 200 mg caffeine in healthy adult volunteers.

- To investigate whether there is a relationship between saliva- and plasma levels of caffeine, and if present, to describe this relationship.

- To determine the effect of saliva pH and/or flow on saliva caffeine concentration.

Study design

Randomized open-label cross-over study.

Intervention

Caffeinated beverage containing approximately 135 mg caffeine or capsule containing 200 mg caffeine.

Study burden and risks

Caffeine has few unwanted side effects and is safe. As only a single relatively low dose of caffeine will be administered per occasion, we do not expect that these side effects occur, with exception of changes in heart rate and blood pressure and short-term increased diuresis.

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

- Subject must be 18-35 years of age (inclusive)
- Subject has a Body Mass Index (BMI) between 18 and 30 kg/m2 (inclusive) and body weight between 50 kg and 90 kg (inclusive);
- Subject is able to read and understand the written consent form, complete study-related procedures, and communicate with the study staff;
- Subject is willing to comply with study restrictions.

Exclusion criteria

- Clinically relevant abnormal history of physical and mental health as determined by medical history taking and physical examinations obtained during the screening visit (as judged by the investigator);
- Clinically relevant abnormal laboratory results, ECG, vital signs, or physical findings at screening (as judged by the investigator);
- Positive test for hepatitis B, C or HIV at screening;
- Positive urinary pregnancy test (females only) at screening;
- History of alcoholism or substance abuse within three years prior to screening;
- Male subjects habitually using more than 21 units of alcohol per week and female subjects using more than 14 units of alcohol per week;
- Positive urine drug screen at screening;
- Subject uses more than 5 units of xanthine-containing food products or drinks (including but not limited to coffee, tea, Red Bull, chocolate) daily;
- Subject is a smoker (> 5 cigarettes per day) or has used nicotine/nicotine-containing products within 3 months prior to screening;
- Subject is unable to refrain from the use of disallowed concomitant medication, dietary

supplements or food products from one week prior to the first caffeine administration until the end of the last occasion;
- Subject is unable to refrain from food and drinks containing a xanthine (e.g. chocolate, cola, energy drinks, coffee or tea) from from 3 days prior to until the end of the study days;
- Participation in an investigational drug study within 90 days prior to the first dose and/or participation in more than 4 clinical trials in the last year;
- Donation or loss of blood (> 500 mL) within 3 months prior to screening.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-06-2012
Enrollment:	6
Type:	Actual

Ethics review

Approved WMO

Date:	31-05-2012
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL40371.058.12