A human capsaicin model to quantitatively assess salivary CGRP secretion

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1. To quantify the CGRP response after application of red chili pepper extract2. To find the optimal concentration of red chilli homogenate containing capsaicin for this response3. To assess day-to-day variability.

Ethical review	Approved WMO
Status	Pending
Health condition type	Cranial nerve disorders (excl neoplasms)
Study type	Interventional

Summary

ID

NL-OMON37224

Source
ToetsingOnline

Brief title
Salivary CGRP

Condition

- Cranial nerve disorders (excl neoplasms)

Synonym
Trigeminal conditions

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: NWO

Intervention

Keyword: Capsaicin, CGRP, Saliva

Outcome measures

Primary outcome

CGRP in saliva in pg/ml

Secondary outcome

The sensation of heat on a scale of 1-10.

Study description

Background summary

Capsaicin is derived from hot peppers of the Capsicum genus and binds to transient receptor potential channels, such as the TRPV1 (formerly known as vanilloid receptor type 1). Activation of the vanilloid receptors on trigeminal nerve terminals causes the release of calcitonin gene-related peptide (CGRP, a 37 amino-acid inflammatory neuropeptide) as well as other inflammatory mediators, also from the major salivary glands and buccal mucosa. The salivary CGRP response after capsaicin might reflect the *activation state* of the trigeminal nerve, innervating the salivary glands. However, quantification of CGRP release after dermal capsaicin application is difficult. Application of capsaicin in the oral cavity also activates trigeminal nerve endings and the subsequent release of CGRP in saliva can be quantified in animals. In humans there are no good reference studies yet. This, however, is useful since it enables to study a variety of trigeminal conditions including headaches non-invasively and prospectively.

Study objective

1. To quantify the CGRP response after application of red chili pepper extract
2. To find the optimal concentration of red chilli homogenate containing capsaicin for this response
3. To assess day-to-day variability.

Study design

Intervention study

Intervention

The application of red chilli homogenate to the oral cavity

Study burden and risks

The burden of this study consits of the time the participants have to invest in the study (110 min)

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 between 18 and 55 years

Male or female
Body mass index between 18 and 30 kg/m2
Capable and willing to give informed consent
General good health

Exclusion criteria

Any serious illness that can compromise study participation
Use of any medication (e.g., NSAIDs, other analgesics) < 48 hrs before the study
History of sensitivity to the fruits of capsicum plants (e.g. chilli peppers)
Alcohol or drug abuse
History of migraine

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2012
Enrollment:	12
Type:	Anticipated

Ethics review

Approved WMO

Date:	20-11-2012
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (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	NL41323.078.12