

Risk Taking and decision-making in cluster headache patients

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Do people with cluster headache exhibit an increased tendency towards risk- and reward-seeking behaviour as quantified by an array of psychometric tests and the Balloon Analogue Risk Task (BART), compared to age- and sex-matched healthy controls and...

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

Summary

ID

NL-OMON48472

Source

ToetsingOnline

Brief title

RiCH

Condition

- Other condition

Synonym

Hortons neuralgie; cluster headache

Health condition

Hoofdpijn

Research involving

Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

Source(s) of monetary or material Support: Beat the Beast

Intervention

Keyword: Cluster headache, Personality, Risk seeking

Outcome measures

Primary outcome

- Psychometric test (subjective): Total score on the Zuckerman Sensation

Seeking Scale

- Balloon Analogue Risk Task (BART, objective): Total number of pumps during second trial

Secondary outcome

- Total scores on the array of psychometric tests

o The Zuckerman*s Sensation Seeking Scale version-V (SSS-V) * a general measure of sensation-seeking

o The Barret Impulsiveness Scale (BIS) * a 30 item questionnaire designed to assess the personality/behavioural construct or impulsiveness.

o Gormally*s Binge Eating Scale (BES) * a 16 item questionnaire which has been used in studies on eating behaviours to diagnose binge eating disorder.

o The World Health Organization-developed AUDIT (Alcohol Use Disorders Identification Test) screen * a 10-question screening tool, developed by the WHO, which has been designed as a as a simple and brief method of screening for excessive drinking.

o The CAGE questionnaire for substance abuse-adapted to include drugs * a

4-question tool widely used in primary care clinics as an initial screen for alcohol and substance abuse.

- o Gamblers Anonymous's 20 Questions (GA20) * a screening tool for detection of problematic gamblers.

- o Hospital Anxiety and Depression Scale (HADS) * a 14 item questionnaire designed to assess anxiety and depression in the general population.

- o Additional screening questionnaire (ASQ) * Based on a questionnaire developed in a previous study to assess life-time drug use with the addition of questions about tattoos and previous head trauma.

- Total scores on the BART

Study description

Background summary

Cluster headache is a severe primary headache disorder. In clinical anecdotes, people with cluster headache frequently report use of tobacco and illicit drugs. Furthermore, addictive behaviours and tattoos are considered to be more common in people with cluster headache than in the general population. The causality of these associations remains unclear. A common biological susceptibility has been proposed, predisposing people to both addictive behaviour and cluster headache. On the other hand, a role of illicit drug exposure in cluster headache pathophysiology has been suggested. The increased use of tobacco and illicit drugs could also reflect attempts to treat cluster headache attacks. In this explorative study we will assess both subjective and objective measures reflecting addictive behaviour and risk- and reward seeking in cluster headache. This will add to the clinical knowledge of cluster headache and possibly lead to insights in a common biological susceptibility.

Study objective

Do people with cluster headache exhibit an increased tendency towards risk- and reward-seeking behaviour as quantified by an array of psychometric tests and the Balloon Analogue Risk Task (BART), compared to age- and sex-matched healthy

controls and compared to age- and sex-matched people with migraine?

Study design

Case-control study

Study burden and risks

There is no risk associated with participation in this study. To minimize the burden, the questionnaires and BART will be performed, if possible, on the same day as the outpatient hospital visit.

Since questionnaires will be administered regarding addictive behaviour and personality and these questionnaires will be scored, participants are asked beforehand if they would like to be informed about the results. It will be stressed however that a diagnosis cannot be made by a questionnaire and the results will only be indicative.

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

Inclusion Criteria * Cluster Headache (eCH & cCH) group:

- * Age 18-64 years

- * Normal or corrected vision with acuity up to 20/60

- * Presence of episodic ($n \leq 35$) or chronic ($n \leq 35$) cluster headache, diagnosed according to the International Classification of Headache Disorders criteria, 3rd edition (ICHD-3, 3.1.1)

;Inclusion Criteria * Migraine group:

- * Age 18-64 years

- * Normal or corrected vision with acuity up to 20/60

- * Presence of migraine with or without aura, diagnosed according to the International Classification of Headache Disorders criteria, 3rd edition (ICHD-3, 3.1.1)

- * Matched to CH patients in age, sex. ;Inclusion Criteria * Healthy Controls:

- * Age 18-64 years

- * Normal or corrected vision with acuity up to 20/60

- * Matched to CH patients in age, sex.

Exclusion criteria

- * Diagnosis of uncorrected visual problems (myopia/presbiopia, peripheral vision problems or legal blindness)

- * Current diagnosis of generalized anxiety disorder, depression or other psychiatric illness

- * Other acute, unstable medical conditions or serious chronic diagnoses

Study design

Design

Study type: Observational non invasive

Intervention model: Other

Allocation: Non-randomized controlled trial

Masking: Open (masking not used)

Control: Active

Primary purpose: Other

Recruitment

NL
Recruitment status: Recruiting
Start date (anticipated): 23-04-2019
Enrollment: 140
Type: Actual

Ethics review

Approved WMO
Date: 11-04-2019
Application type: First submission
Review commission: METC Leiden-Den Haag-Delft (Leiden)
metc-ldd@lumc.nl

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	NL68327.058.18