Blink reflex changes following oxygen therapy in active cluster headache

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

Summary

ID

NL-OMON37298

Source
ToetsingOnline

Brief title
Blink reflex changes following oxygen therapy in active cluster headache

Condition

- Headaches

Synonym
cluster headache, Horton headache

Research involving
Human

Sponsors and support

Primary sponsor: Atrium Medisch Centrum
Source(s) of monetary or material Support: geen geldstroom

Intervention

Keyword: blink reflex, cluster headache, oxygen, oxygen therapy

Outcome measures

Primary outcome

The main study endpoints are differences in R2 latency, amplitude, duration, area and habituation measured on both sides between the time points: before a cluster headache attack (without oxygen treatment), immediately after start of the cluster headache attack and after 12-15 minutes of oxygen treatment for the cluster headache attack.

Secondary outcome

The secondary study endpoints are differences in change of R2 latencies, amplitudes, durations, areas and habituation in the 12-15 minutes of oxygen treatment between the groups: clear responders (reduction of pain of at least 50% within 15 minutes after the start of oxygen inhalation) and non-responders plus moderate responders (reduction of pain of less than 50% within 15 minutes after the start of oxygen inhalation); differences in R2 latency, amplitude, duration, area and habituation at the aforementioned 3 time points between the symptomatic and asymptomatic side; differences in R2 latency, amplitude, duration, area and habituation before a cluster headache attack without and with oxygen treatment.

Study description

Background summary

In order to further unravel the pathophysiology of cluster headache, we want to determine the location at which oxygen exerts its pain reducing effects in humans. We hypothesize a neurogenic effect of oxygen at brainstem level. As a substitute for measurement of impairment of parasympathetic outflow and to determine the influence of interneurons on the trigemino-facial reflex arch, we will look at the effect of oxygen on medullary interneurons by using the *nociception specific* blink reflex.

Study objective

The primary objective is to measure R2 latencies, amplitude, duration, area and habituation of the electrically evoked *nociception specific* blink reflex before and after treatment with oxygen at a flow rate of 12 L/min during a cluster headache attack.

Study design

Repeated measures: the *nociception specific* blink reflex will be measured before a spontaneous cluster headache attack (without and with oxygen treatment), shortly after the onset of the attack and 12-15 minutes after the start of treatment with 100% oxygen.

Intervention

All patients will be treated with 100% percent oxygen at a flow rate of 12 L/minute, given 3 minutes after pain onset for 15 minutes, using a non-rebreathing facial mask.

Study burden and risks

Before starting the first blink reflex measurement patients will have to fill in a questionnaire. * Patients will undergo at least four blink reflex measurements during one visit: the blink reflex will be elicited every 2 hours before the onset of a cluster headache attack without oxygen treatment, once before the onset of a cluster headache attack during oxygen treatment, at the onset of the cluster headache attack and 12-15 minutes after the start of oxygen treatment. The stimulations during the blink reflex measurements will produce a pinprick-like pain. * During the first 3 minutes of the cluster headache attack (i.e. during the first blink reflex measurement during the cluster headache attack) the patient will not receive oxygen treatment. However, we assume that this reflects the patient*s situation at home. * Oxygen entails a fire hazard. Very rare side effects of oxygen treatment are pleuritis and respiratory distress syndrome. * The VAS pain score (of 0-10) will be asked for at the onset of the cluster headache attack, at 3 minutes after the onset of the cluster headache attack (i.e. at the start of oxygen treatment) and at 15 and 18 minutes after the onset of the cluster headache attack.

The study will not provide an immediate benefit for the individual participating patient. This study will contribute to a better understanding of cluster headache pathophysiology. A better understanding of the disease pathophysiology will lead to more targeted and therefore probably more effective treatment or applications of treatment in the future, leading to better pain relief and/or prevention of pain.

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

1. Episodic or chronic cluster headache according to the ICHD-II criteria , diagnosed by a neurologist.
2. Episodic cluster headache patients have to be in a cluster period.
3. Age 18-70 years.

Exclusion criteria

1. Secondary cluster headache, as diagnosed by the patient*s neurologist.
2. Other primary or secondary headache diagnoses or other painful conditions which could interfere with the patient*s pain perception.
3. Pregnancy or lactation.
4. Chronic obstructive pulmonary disease and other contraindications for oxygen therapy.
5. Intolerability of the oxygen face mask.
6. Rebound cluster headache following oxygen therapy .
7. Previous surgical treatment of the trigeminal nerve or thermolesion of the sphenopalatine ganglion.
8. Side change of cluster headache in the previous year.
9. Incapacitation to understand and sign for informed consent.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-09-2012
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	10-07-2012
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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	NL41155.096.12