Veranderingen in de blink reflex ten gevolge van zuurstoftherapie voor actieve clusterhoofdpijn.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22660

Source
Nationaal Trial Register

Health condition

Blink reflex, oxygen, oxygen therapy, cluster headache. Blink reflex, zuurstof, zuurstofbehandeling, clusterhoofdpijn

Sponsors and support

Primary sponsor: Dept. of Neurology, Atrium Medical Centre, Heerlen
Source(s) of monetary or material Support: Self-financing: sponsor is Dept. of Neurology, Atrium Medical Centre, Heerlen

Intervention

Outcome measures

Primary outcome

Differences in R2 parameters measured on both sides between time points: Before cluster headache (CH) attack, immediately after CH attack onset and after 12-15 min. of oxygen treatment for CH attack.

Secondary outcome

1. Differences in change of R2 parameters in 12-15 min. of oxygen treatment between groups clear responders and non-responders plus moderate responders;

2. Differences in R2 parameters at the aforementioned 3 time points between symptomatic and asymptomatic side;

3. Differences in R2 parameters before a cluster headache attack without and with oxygen treatment.

Study description

Background summary

Rationale:

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.

Objective:

The primary objective is to measure R2 latencies, amplitude, duration and area 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.

Study population:

Episodic cluster headache patients in a cluster period and chronic cluster headache patients, aged 18-70 years, of both genders.

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.

Main study parameters/endpoints:

The main study endpoints are differences in R2 latency, amplitude, duration and area 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.
The secondary study endpoints are differences in change of R2 latencies, amplitudes, durations and areas 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 and area at the aforementioned 3 time points between the symptomatic and asymptomatic side; differences in R2 latency, amplitude, duration and area before a cluster headache attack without and with oxygen treatment.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

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.

Study objective

N/A

Study design

Every 2 hours before cluster headache (CH) attack, immediately after CH attack onset and after 12-15 min. of oxygen treatment for CH attack.

Intervention

100% oxygen at 12 L/min, will be given 3 min. after cluster headache attack onset for 15 min. Blink reflexes will be measured directly after cluster headache attack onset and after 12 min. of oxygen treatment.

Contacts

Public
Atrium medisch centrum
Department of neurology
PO Box 4446

P.J. Koehler
Heerlen 6401 CX
The Netherlands
+31 (0)45-576 67 00
Scientific
Atrium medisch centrum
Department of neurology
PO Box 4446

P.J. Koehler
Heerlen 6401 CX
The Netherlands
+31 (0)45-576 67 00

Eligibility criteria

Inclusion criteria

1. Episodic / chronic cluster headache according to ICHD-II criteria, diagnosed by neurologist;

2. Episodic cluster headache patients have to be in cluster period;

3. Age 18-70 years.

Exclusion criteria

1. Secondary cluster headache, as diagnosed by patient’s neurologist;

2. Other painful conditions which could interfere with patient’s pain perception;

3. Pregnancy or lactation;

4. COPD and other contraindications for oxygen;

5. Intolerability of oxygen face mask;

6. Rebound cluster headache following oxygen therapy;

7. Previous surgical treatment of trigeminal nerve or thermolesion of sphenopalatine ganglion;

8. Side change of cluster headache in previous year;

9. Incapacitation to understand and sign for informed consent.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)

Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	13-09-2012
Enrollment:	20
Type:	Anticipated

Ethics review

Positive opinion

Date:	15-01-2013
Application type:	First submission

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
NTR-new	NL3656
NTR-old	NTR3802
Other	METC Atrium MC-Orbis-Zuyd : 12-T-66
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A