Oxygen treatment for cluster headache attacks at different flow rates. A double-blind, randomized, cross-over design study.

Published: 10-09-2012
Last updated: 26-04-2024

Primary: To study whether there is a difference in treatment effect between oxygen at flow rates of 7 L/min versus 12 L/min in the acute treatment of cluster headache attacks.
Secondary: - Identifying subgroups in which oxygen at flow rates of 7 L/…

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

Summary

ID

NL-OMON37264

Source
ToetsingOnline

Brief title
CLATOXYT (CLuster headache ATtacks OXYgen Treatment)

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; de voorgeschreven zuurstofbehandeling valt onder de zorgverzekering van de patiënt,Westfalen Medical BV verzorgt een deel van de logistiek en levert aangepaste zuurstofcilinders aan huis

Intervention

Keyword: cluster headache, oxygen, oxygen flow rates, oxygen treatment

Outcome measures

Primary outcome

The primary endpoint is the difference in VAS score before and after oxygen

treatment.

Secondary outcome

The secondary endpoint is the percentage of successfully treated attacks as

defined by a drop in VAS score of over 50% within 15 minutes.

Study description

Background summary

Oxygen is frequently used as an acute attack treatment for cluster headache. Studies have showed the beneficial effect of oxygen compared to placebo at flow rates of 7 L/min and 12 L/min. Three patients who did not respond to 7-10 L/min but did so to 14-15 L/min were described in a case report. The difference in effect between 7 L/min and 12 L/min, however, has never been investigated in a controlled study. This might aid the clinician in making an appropriate decision when prescribing oxygen.

Study objective

Primary:
To study whether there is a difference in treatment effect between oxygen at flow rates of 7 L/min versus 12 L/min in the acute treatment of cluster headache attacks.
Secondary:
- Identifying subgroups in which oxygen at flow rates of 7 L/min or 12 L/min is more effective.
- To determine whether the rebound effect known to occur in oxygen treatment is

more frequently observed in one of the different flow rates or whether this is an effect independent from the flow rates used.
- To note any potential side-effects of oxygen treatment, and if observed, determine if they occur more in either 7 L/min or 12 L/min.
- To determine if the efficacy of oxygen treatment stays constant after several treated attacks.

Study design

Double-blind cross-over design study, in which every patient will treat his attacks with either oxygen at 7 L/min or 12 L/min for a total of 4 time periods, each lasting 3 days. There will be no set amount of attacks to be treated in each time period.

Intervention

Patients will be crossed-over between treatment with oxygen at a flow rate of 7 L/min and 12 L/min. Treatment will be continued until the cluster headache attack has ended or for 15 minutes.

Study burden and risks

Patients will have to fill in two questionnaires: one before and one after the study. During the treatment they will have to fill in a diary to describe the effect of the various treatments. A possible side-effect of oxygen usage is dyspnea caused by hypoventilation or atelectasis.
Furthermore heart rate and cardiac output might be reduced when 100 % oxygen is administered for short periods (< 6 hours) under normobaric conditions. In patients who are dependent of oxygen as a stimulus for breathing (COPD patients), oxygen treatment might lead to acidosis.
Further side effects have only been described in continuous oxygen usage.
As oxygen entails a fire hazard, patient will be adequately informed in the usual way by the oxygen supplier.

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

All newly diagnosed cluster headache patients of at least 18 years of age and known cluster headache patients of at least 18 years of age who are naïve to oxygen treatment.

Exclusion criteria

- All patients who used oxygen in the past.
- Pregnancy or lactation.
- COPD and other contraindications for oxygen therapy, as determined by the patients* physicians.
- Secondary cluster headache. Patients might be included before imaging is conducted. If so, they will be excluded afterwards when they are diagnosed as secondary cluster headache.
- Other primary or secondary headache diagnoses or other distracting painful conditions which could interfere with the patient*s pain perception.
- Incapacitation to understand and sign for informed consent.
- Patients living outside a designated insurance zone, as costs of the adapted oxygen tanks will not be covered elsewhere.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-03-2013
Enrollment:	100
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Oxygen, compressed
Generic name:	Oxygen, compressed
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	10-09-2012
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	01-10-2012
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	17-01-2013
Application type:	Amendment

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
EudraCT	EUCTR2012-003648-59-NL
CCMO	NL41818.096.12