Zuurstoftherapie met verschillende stroomsnelheden voor clusterhoofdpijnaanvallen. Een dubbelblinde, gerandomiseerde, cross-over design studie.

Gepubliceerd: 14-01-2013 Laatst bijgewerkt: 18-08-2022

N/A

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23355

Bron
NTR

Verkorte titel
CLATOXYT

Aandoening

Cluster headache; oxygen; oxygen treatment; oxygen flow rates. Clusterhoofdpijn; zuurstof; zuurstofbehandeling; zuurstof stroomsnelheden

Ondersteuning

Primaire sponsor: Dept. of Neurology, Atrium Medical Centre, Heerlen
Overige ondersteuning: Self-financing: sponsor is Dept. of Neurology, Atrium Medical Centre, Heerlen

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Difference between the flow rates of 7 and 12 L/min in percentages of achievement of a painfree state after 15 minutes of treatment with oxygen, given in at least 2 attacks/day on the first 2 days.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

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.

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:

1. Identifying subgroups in which oxygen at flow rates of 7 L/min or 12 L/min is more effective;

2. 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;

3. 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.

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 6 time periods, the first 2 lasting 1 day each and the last 4 lasting 3 days each. In the first 2 days at least 2 attacks/day have to be treated with oxygen. There will be no set amount of attacks to be treated in each time period lasting 3 days.

Study population:

Newly diagnosed cluster headache patients (≥18 years old) or cluster headache patients who have not used oxygen before (oxygen naïve).
Both episodic and chronic cluster headache patients will be eligible for this study.

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.

Main study parameters/endpoints:

The primary endpoint will be a difference between the flow rates of 7 and 12 L/min in percentages of achievement of a painfree state after 15 minutes of treatment with oxygen, given in at least 2 attacks/day on the first 2 days. The secondary endpoints will be the difference between the flow rates of 7 and 12 L/min in percentage of attacks treated successfully, the difference between the flow rates of 7 and 12 L/min in drop in VAS score and percentages of patients preference to the flow rates of 7 and 12 L/min, in the 4 treatment periods (i.e. day 3 till 14).

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

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.

Doel van het onderzoek

N/A

Onderzoeksopzet

1. Start of oxygen treatment during cluster headache attack;

2. After 15 minutes of oxygen treatment during cluster headache attack;

3. 6 time periods in 14 days.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

Atrium medisch centrum
Department of neurology
PO Box 4446

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

Wetenschappelijk

Atrium medisch centrum
Department of neurology
PO Box 4446

P.J. Koehler
Heerlen 6401 CX

The Netherlands
+31 (0)45-576 67 00

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Cluster headache patients of at least 18 years of age, who are naïve to oxygen treatment.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Past oxygen use;

2. Pregnancy or lactation;

3. COPD and other contraindications for oxygen;

4. Secondary cluster headache;

5. Distracting painful conditions;

6. Incapacitation to understand and sign for informed consent;

7. Patients living outside a designated insurance zone;

8. Raise of dose of prophylactic medication in first 2 days of study.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind

Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-03-2013
Aantal proefpersonen:	108
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	14-01-2013
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3655
NTR-old	NTR3801
Ander register	METC Atrium MC-Orbis-Zuyd : 12-T-95
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A