Treatment of headaches post-ECT with oxygen therapy; a proof of concept study

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Headaches
Study type	Interventional

Summary

ID

NL-OMON48593

Source
ToetsingOnline

Brief title
Oxygen to treat headache post-ECT

Condition

- Headaches
- Psychiatric disorders NEC

Synonym
Headache, post-ECT headache

Research involving
Human

Sponsors and support

Primary sponsor: Reinier van Arkelgroep (Den Bosch)
Source(s) of monetary or material Support: Dit onderzoek wordt niet gefinancierd. De grootste kostenpost van dit onderzoek zijn de personele kosten welke worden betaald door de Reinier van Arkel groep (de instelling zelf).

Intervention

Keyword: ECT, Headache, Oxygen

Outcome measures

Primary outcome

Primary Objective:

Reducing headache complaints after an ECT treatment: A treatment effect is defined as a reduction of the headache on the VRS of a score >= 2 (moderate / severe) before administration of oxygen to <=1 (no or light) immediately after administration of oxygen (about 20 minutes post-ECT).

Secondary outcome

Secondary Objective (s):

Time to reduce headache symptoms: It is expected that the effect of oxygen treatment on the headache symptoms occurs immediately after the administration of oxygen, as is the case with cluster headache.

Duration of the treatment effect: The effect of oxygen treatment against headache is expected to last for at least 2 hours.

Incidence and course of headache. In addition to the effect of oxygen therapy on headache complaints, the data will be used to investigate the incidence and course of headache complaints after ECT.

Hypothesis:

The severity of headache complaints post ECT will decrease after oxygen

therapy.

Study description

Background summary

In the Netherlands, approximately 700 patients with severe depression and other psychiatric disorders are treated with electroconvulsive therapy (ECT) each year. ECT is a safe treatment option, and has few serious side effects. Nevertheless, approximately half of the patients treated with ECT experience headache after treatment. These complaints range from mild to severe, progressively increase after treatment but rarely last longer than 24 hours. In severe cases, this side effect may be a reason for the patient to refrain from further ECT treatments.
The etiology of post-electroconvulsive headache is still unclear. The fact that ECT is associated with vascular changes in the brain, and the pulsating nature of the headache after ECT with sometimes additional nausea and vomiting, suggests a vascular origin. This presumption is confirmed by investigations into the apparent effectiveness of, among others, sumatriptan and propranolol in headache after ECT. Both drugs are used in the treatment of migraine and cluster headache, which have probably a vascular origin as well. An effect of treatment with oxygen on post-electroconvulsive headache can contribute to the knowledge about the pathophysiology of post-electroconvulsive headache.
Post-electroconvulsive headache is currently symptomatically treated with analgesics, including paracetamol, NSAID*s and opiates. This treatment is effective for most patients. For patients with persistent headache after ECT despite treatment, the above-mentioned agents (propranolol, sumatriptan, dihydroergotamine) may be an option. In view of side effects, contraindications and drug interactions, the possibility of a non-medication treatment makes an important contribution. It is expected that (through shared decision making) patients will have a strong preference for a non-medication therapy.
Normobare oxygen therapy is the first choice for acute cluster headache. The mechanism of action of this therapy is unknown, but may be understood through vasoconstriction of meningeal vessels.
Oxygen therapy does not have any relevant side effects and no drug interactions are known. There is no absolute contraindication for oxygen administration.
The administration of oxygen through a nasal mask has proved effective in our clinic in some patients with treatment-resistant headache after ECT. To further investigate the effectiveness of this treatment, we first want to carry out a proof of concept study of which we intend to publish the results. If oxygen therapy appears to be an effective intervention in this study, a placebo-controlled follow-up study will be conducted.

Study objective

The purpose of the study is to investigate the effectiveness of oxygen therapy in headache after ECT.
No research has been conducted into a non-medical treatment of headache after ECT. Oxygen therapy is potentially a quick, inexpensive, and safe way to relieve headache after ECT, without any danger to the patient. The intervention to be investigated is hardly burdensome.

Study design

It concerns a proof of concept study.

Every year about 70 patients in the Jeroen Bosch Hospital, unit Hospital Psychiatry, Elderly and cognition (ZPO), part of Reinier van Arkel, are treated with ECT. Based on this study, we expect approximately half of this patient population to have post-ECT headache symptoms. The indication for ECT is set in a special ECT indication consultation. After this consultation an appointment is planned with the patient for a preoperative screening which is performed by an anaesthesiologist at the service of the Jeroen Bosch Hospital.

Both patients starting with ECT and existing ECT patients are approached for the study. All patients 18 years of age and older who are willing and will be treated by ECT are asked orally during the ECT intake by their doctor if they are interested in participating in this study. If the patient is interested in participation, this will be approached by the researcher. This will inform the patient in detail about the research. The patient information letter and the informed consent will be provided to the patient at that time. The study gives the patient a week of reflection time to decide on participation. A week later the researcher contacts the telephone to ask if the patient wants to participate. If the patient needs more reflection time, this is possible.
If the patient wants to participate, he / she is asked to take the informed consent form signed with them to the first ECT treatment.
In the case of permission, the researcher will check before the start of the first ECT whether the patient meets the inclusion and exclusion criteria.
If so, the researcher will assign a unique code to the participant. The overview of the names of the participants with corresponding codes is stored in a protected folder on the network of Reinier van Arkel. In addition to the researcher, the ECT nurses and research staff also have access to this file. After receiving permission, they receive an email with the secured data from the included patients.

Patients participating in the study will be marked with a sticker on the patient board at the nursing office, with a reference on the ECT schedule of that day, and with a clearly colored cover sheet on the ECT folder that is included with each ECT patient. room and will accompany the patient with each treatment. The sticker on the patient board, the reference in the ECT roster, and the cover page in the ECT folder are provided by the research assistant. The research assistant also ensures that a research protocol and VRS forms are

included in the ECT folder. The oxygen delivery equipment will be prepared by the duty nurse in the evening shift when, in accordance with the existing ECT protocol, they also provide other preparations for the ECT treatment the next day. The VRS form contains the unique patient code and the number of times the patient participates in the study (each patient is allowed to participate a maximum of three times).

With every ECT treatment, the ECT nurse will ask whether the patient has used oily skin on the face that day, as is also the case with the usual ECT protocol. Because of the possible need to administer oxygen during the ECT treatment, for example in the event of complications arising from anesthesia, the use of oily skin is already banned to any patient, regardless of participation in this study.

Just before the start of the ECT, the research assistant will ask the patient if he / she suffers from headaches and if so to what extent. Patients are taken to the recovery room after the ECT. When the patient is awake, the ECT nurse will take the OK bed to their own room. Upon arrival at the department, the research assistant is informed that the patient is back in his / her room and whether he / she is participating in the study. The research assistant goes to the patient's room and asks for headaches. Headache will be measured by means of a validated 4-point headache scale that is used, among other things, to objectify headache symptoms in cluster headache, the Verbal Rating Scale (VRS): 0 = no pain; 1 = mild pain; 2 = moderate pain; and 3 = severe pain.
Patients who have headaches for ECT (VRS score> 0) are excluded from participation. If there are no headaches before ECT, immediately after ECT, 60 minutes after ECT, and 120 minutes after ECT, headache complaints will be asked again and scored by the VRS. At a score> 0, the patient will be treated with 100% oxygen, 7 liters per minute for 20 minutes lying on bed by means of a mask. The oxygen is connected by a nurse in the department. After 20 minutes the oxygen is shut down by a nurse.
Then another VRS is taken by the research assistant.
When the headache symptoms last longer than 2 hours after oxygen therapy they will switch to regular pain medication (paracetamol, NSAID) if desired by the patient. Patients can ask for this themselves.
The VRS form is returned to the ECT folder by the research assistant. When all patients of that day have undergone ECT treatment, the research assistant will collect the VRS forms from the folders. The forms are handed over to the researcher and processed by him.

To exclude random findings, three rechallenges are chosen. This means that one subject participates a maximum of three times in the study on three different ECT treatment days, if oxygen treatment takes place. The VRS measurements will be done after inclusion after each ECT treatment. The repeated measurements provide insight into the robustness of the effects of oxygen therapy.

The course of the research and the logistical matters are monitored by the

researcher and by the research staff and adjusted where necessary.

Intervention

As discussed, there are indications for a vascular origin of post-ECT headache. Due to the fact that cluster headache presumably has a vascular origin as well, it is decided to treat patients in this study according to the same guidelines as used in oxygen therapy in cluster headaches:

100% oxygen, 7 liters per minute, for 20 minutes, via a face mask.

Study burden and risks

- Appearance of fire. The danger is minimized. Smoking is not allowed in the rooms. In addition, this risk will be communicated to patients, prohibiting open fire during oxygen treatment.
- There is a risk of hypercapnia in patients with COPD. These patients are being excluded. If an included patient is not (yet) diagnosed with COPD, but has it anyway, oxygen treatment for twenty minutes does not constitute a clinically relevant risk because the condition is likely to be mild in that case.
- In combination with the oncolytic bleomycin, lung toxicity may occur, sometimes months after discontinuation of bleomycin. Patients who are currently be treated with bleomycin, or has been in the last 12 months, are excluded from the study.

The load of the study consists of the 20-minute bedtime during the oxygen treatment, where patients could go elsewhere in these 20 minutes and where they want. This tax is considered to be minimal since patients suffering from headache complaints are likely to be more comfortable than being stressed. In addition, a maximum of three times per patient is asked for the degree of headache. The nurse completes this score on the score form.

Contacts

Public
Reinier van Arkelgroep (Den Bosch)

Henri Dunantstraat 1
's-Hertogenbosch 5223GZ
NL
Scientific
Reinier van Arkelgroep (Den Bosch)

Henri Dunantstraat 1
's-Hertogenbosch 5223GZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Age older than 18
- Indication for ECT treatment for psychiatric illnesses.
- Treated in the department ZPO of the Reinier van Arkel groep

Exclusion criteria

- COPD
- Current use of bleomycine, or in the past 12 months
- Patients with a custody measure
- Patients who are mentally incompetent regarding the decision of participation in the study, or undergo trial operations
- Patients who suffer from panic attacks
- Patients with a VRS score of >0 pre ECT

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	18-01-2019
Enrollment:	27
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Oxygen medicinal fluid AIR LIQUIDE, medicinal gas, cryogen 100% v/v
Generic name:	Medical oxygen
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO

Date:	06-06-2018
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date:	27-06-2018
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date:	16-01-2019
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date:	17-01-2019
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	EUCTR2018-001763-23-NL
CCMO	NL62562.068.18