Lucht via de neus als behandeling voor medicatie-afhankelijke hoofdpijn ten gevolge van overgebruik van triptanen

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Medication overuse headache (MOH) is a disorder that results from the overuse of analgesics, triptans or other acute headache medication. Patients overusing triptans are almost always patients with migraine as their primary headache. There is...

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

Samenvatting

ID

NL-OMON24899

Bron
Nationaal Trial Register

Aandoening

Chronic migraine with triptan-overuse headache

Ondersteuning

Primaire sponsor: H. Koppen, MD, neurologist, HagaZiekenhuis
Overige ondersteuning: No financial support

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Number of hours with severe or moderate headache in the first 7 days.
Headache will be scored on a four-point scale: 0 = no headache, 1 = mild headache, 2 = moderate headache and 3 = severe headache.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

Medication overuse headache (MOH) is a disorder that results from the overuse of analgesics, triptans or other acute headache medication. Patients overusing triptans are almost always patients with migraine as their primary headache. There is general agreement that the only treatment of MOH is withdrawal of the overused medication (eg detoxification). In general, no other analgesics (rescue medication) are permitted during detoxification, as subjects tend to risk overusing this rescue medication also. Discontinuation of the overused headache medication often results in the development of withdrawal headache, often associated with nausea, vomiting, photophobia, phonophobia, sleep disturbances, restlessness and nervousness. In general and especially in the case of triptan overuse, the first week of detoxification is most difficult, resulting in the frequent failure of the detoxification process and subjects continuing to overuse their medication. Today no alternative treatment for withdrawal headache during triptan detoxification exists.

Objective:

The aim of this study is to investigate the effect of the RhinoChill nasal cavity Cooling System (RhinoChill System) on severity and frequency of withdrawal headache and associated symptoms in the first 7 days during standard care treatment for detoxification of triptan-overuse headache as compared to sham treatment during standard care treatment.

Study Design:

A prospective, multicenter, double-blinded, sham-controlled, randomized controlled trial.

Study population:

Adult patients with migraine and triptan-overuse headache who are admitted for detoxification due to overuse of triptan medication.

Intervention:

In-hospital application with up to 10 minutes of nasal cavity cooling per treatment with the RhinoChill System (with further treatments every 2 hours, if required, up to a maximum of 4 treatments per 24 hours and maximum of 24 treatments in 7 days), along with standard care treatment versus sham-RhinoChill (only air without cooling) with standard care treatment.

Primary end point:

Number of hours with severe or moderate headache in the first 7 days.

Hypothesis:

The hypothesis we propose is that the application of RhinoChill nasal cavity cooling will provide effective relief of withdrawal headache and associated symptoms, in patients with triptan-overuse headache in the first week of detoxification.

Doel van het onderzoek

Medication overuse headache (MOH) is a disorder that results from the overuse of analgesics, triptans or other acute headache medication. Patients overusing triptans are almost always patients with migraine as their primary headache. There is general agreement that the only treatment of MOH is withdrawal of the overused medication (eg detoxification).

The aim of this study is to investigate the effect of the RhinoChill nasal cavity Cooling System (RhinoChill System) on severity and frequency of withdrawal headache and associated symptoms in the first 7 days during standard care treatment for detoxification of triptan-overuse headache as compared to sham treatment during standard care treatment.

The hypothesis we propose is that the application of RhinoChill nasal cavity cooling will provide effective relief of a withdrawal headache and associated symptoms, in patients with triptan-overuse headache in the first week of detoxification.

Onderzoeksopzet

Primary outcome: 1 week

Secondary outcomes: 1 week and 8 weeks

Onderzoeksproduct en/of interventie

In-hospital application with up to 10 minutes of nasal cavity cooling per treatment with the RhinoChill System (with further treatments every 2 hours, if required, up to a maximum of 4 treatments per 24 hours and maximum of 24 treatments in 7 days), along with standard care treatment versus sham-RhinoChill (only air without cooling) with standard care treatment.

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

A. Age ¡Ý 18 and ¡Ü70 years of age.

B. Migraine diagnosis established before by neurologist.

C. Diagnosis of triptan overuse headache according to the diagnostic criteria of the International Headache Society, 3rd edition (beta version).

D. Patient suitable for admission for an in-patient detoxification programme.

E. Able to attend a short training session on the practical use of the RhinoChill device and agrees to only use the device as instructed and as laid out in the official instructions for use.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

A. < 18 and > 70 years of age.

B. Only overuse of simple analgesics, defined as the use of simple analgesics (acetaminophen, NSAID¡¯s) in ¡Ý15 days / month.

C. Change of preventive migraine medication in the previous 3 months.

D. Abuse of alcohol of other elicit drugs (DSM criteria).

E. Known oxygen dependency to maintain SaO2 >95%.

F. Currently uncontrolled hypertension with Systolic BP > 160 mmHg and Diastolic BP > 95mmHg on baseline assessment.

G. Marked nasal septal deviation, recurrent epistaxis or chronic rhino-sinusitis.

H. Intranasal obstruction preventing full insertion of nasal catheter.

I. Known acute base of skull fracture or facial trauma (in previous 2 months).

J. Concurrent sinus/intranasal surgery (in previous 2 months or next 2 months).

K. Medical history of thrombocytopenia.

L. Previous stroke or myocardial infarction.

M. Unable to fully understand the consent process and provide informed consent due to either language barriers or mental capacity.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Factorieel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	19-05-2017
Aantal proefpersonen:	80
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	18-05-2017
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 47266
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6278
NTR-old	NTR6452
CCMO	NL60091.098.16
OMON	NL-OMON47266

Resultaten