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

No registrations found.

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

Summary

ID

NL-OMON24899

Source
Nationaal Trial Register

Health condition

Chronic migraine with triptan-overuse headache

Sponsors and support

Primary sponsor: H. Koppen, MD, neurologist, HagaZiekenhuis
Source(s) of monetary or material Support: No financial support

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

- Headache response, defined as improvement of pain from severe/moderate to mild/none immediately following treatment (10 minutes), at 1 hour, 2 hours, and 24 hours following treatment. When the RhinoChill System is used before 24 hours because of recurrence of the pain this will be scored as ¡®not applicable¡¯ at 24 hours.

- Time to meaningful relief from withdrawal headache, defined as total minutes after beginning of treatment with RhinoChill System to effect (mild or no headache)

- Time to freedom from pain, defined as total minutes after beginning of treatment with RhinoChill System to effect (no headache)

- Number of hours with withdrawal symptoms in the first 7 days:

o Nausea, scored as: none, mild, moderate or severe o Vomiting, scored as: none, mild, moderate or severe o Photophobia, scored as: none, mild, moderate or severe o Phonophobia, scored as: none, mild, moderate or severe o Restlessness , scored as: none, mild, moderate or severe

- Total amount of days of hospitalization

- Patient satisfaction of the use of the RhinoChill System to manage pain and symptoms of medication overuse withdrawal headache. This will be scored with a Likert scale:

o I am very satisfied by the use of the RhinoChill System to manage pain and associated symptoms, such as nausea and vomiting, photophobia, phonophobia and restlessness, during the first 7 days of withdrawal of triptan overuse headache: Strongly disagree, disagree, neither agree nor disagree, agree, strongly agree.

- Reduction in number of headache days / month with moderate or severe intensity

- Units of used escape medication during initial 7 days and remaining 7 weeks period.

- Reduction in number of migraine days / month. A migraine day is defined as a day with migraine according to diagnostic criteria of the International Headache Society, 3rd edition (beta version), table 1.

- Reduction in number of migraine episodes / month.

- Conversion rate from subjects with chronic migraine (¡Ý 15 days / month) to episodic migraine (< 15 days / month).

- Percentage successful complete withdrawal of triptans during study months, defined as no use of triptans during the detoxification period.

- Conversion rate from subjects using > 10 days triptans to < 10 days triptan use per month.

Study description

Background summary

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.

Study objective

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.

Study design

Primary outcome: 1 week

Secondary outcomes: 1 week and 8 weeks

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.

Contacts

Public
H. Koppen
Els Borst-Eilersplein 275

Den Haag 2545 AA
The Netherlands
070-210 2381
Scientific
H. Koppen
Els Borst-Eilersplein 275

Den Haag 2545 AA
The Netherlands

Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Factorial
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	19-05-2017
Enrollment:	80
Type:	Anticipated

Ethics review

Positive opinion

Date:	18-05-2017
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 47266

Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

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

Study results