Nasal cavity evaporative COOLing for the symptomatic relief of withdrawal HEADache and associated symptoms during triptan-overuse detoxification

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

Summary

ID

NL-OMON47266

Source
ToetsingOnline

Brief title
COOLHEAD3

Condition

- Headaches

Synonym
Medication-overuse headache, triptan-overuse headache

Research involving
Human

Sponsors and support

Primary sponsor: HagaZiekenhuis

Source(s) of monetary or material Support: De RhinoChill apparaten;neuskatheters en flessen met koelvloeistof of placebo worden door de firma BrainCool AB gratis geleverd. Daarnaast is er een subsidie aangevraagd bij het HagaWetenschapsfonds voor financiëring van het transport/versturen van de benodigde flessen tussen de deelnemende centra en kosten voor een statisticus/epidemioloog voor ondersteuning bij schrijven van het protocol.

Intervention

Keyword: Intranasal cooling, Migraine, Triptan-overuse headache

Outcome measures

Primary outcome

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

Secondary outcome

- Headache response 1 hour, 2 hours and 24 hours after treatment.

- Time to meaningful relief from headache after treatment.

- Time to freedom from pain after treatment.

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

vomiting, photophobia, phonophobia, restlessness.

- Total amount of days of hospitalization.

- Patient satisfaction.

- 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 after 2 months.

- Reduction in number of migraine episodes / month after 2 months.

- Conversion rate from subjects with chronic migraine to episodic migraine.

- Percentage successful complete withdrawal of triptans during study months.

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

per month triptan use per month.

Study description

Background summary

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 and frequent overuse triptans (specific migraine medication). 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. 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, in the case of triptan overuse, the first week of detoxification is most difficult. If detoxofication at home is not possible patients can be admitted to the hospital. The severtiy of withdrawal symptoms often results in failure of the detoxification process and subjects continuing to overuse their medication. Today no alternative treatment for withdrawal headache during triptan detoxification exists.

Study objective

The aim of this study is to investigate the effect of the intranasal cooling (RhinoChill System) on the 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.

Study design

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

Intervention

Application of intranasal cooling with the RhinoChill System: up to 10 minutes of nasal cavity cooling per treatment 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.

Study burden and risks

Before inclusion patients are asked to fill in a headache diary and a questionnaire. During the study patients are asked to fill in diaries. During the study patients will visit the outpatient clinical 2 times, standard care is visiting the outpatient clinical for 1 or 2 times (so when participating in the study possible 1 visit extra (besides standard care) will be asked). The device has been CE marked. Intranasal cooling can result in a few (minor) side effects, for example nasal discomfort, runny nose, sneezing, (mild) epistaxis, strange tase or smell and dry eyes. All side effects are minor in nature and resolve spontaneously after discontinuation or completion of the treatment.

Contacts

Public
HagaZiekenhuis

Els Borst-Eilersplein 275
Den Haag 2545 AA
NL
Scientific
HagaZiekenhuis

Els Borst-Eilersplein 275
Den Haag 2545 AA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

A. Age 18 * and * 70 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 *15 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:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-10-2017
Enrollment:	15
Type:	Actual

Medical products/devices used

Generic name:	RhinoChill
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	07-03-2017
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	26-10-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 24899
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL60091.098.16
OMON	NL-OMON24899

Study results

Date completed:	12-08-2019
Actual enrolment:	15