

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

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Ethical review	Not approved
Status	Will not start
Health condition type	Headaches
Study type	Interventional

Summary

ID

NL-OMON42967

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 BeneChill 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.

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 to < 10 days 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 detoxification at home is not possible patients can be admitted to the hospital. The severity 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 multi-center, 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 taste or smell and dry eyes. All side effects are minor in nature and resolve spontaneously after discontinuation or completion of the treatment.

Contacts

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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 or other illicit 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:	Will not start
Enrollment:	80

Type: Anticipated

Medical products/devices used

Generic name: RhinoChill

Registration: Yes - CE intended use

Ethics review

Not approved

Date: 02-05-2016

Application type: First submission

Review commission: METC Leiden-Den Haag-Delft (Leiden)

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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

CCMO

ID

NL57223.098.16